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ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

HEARING

BEFORE THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

EXAMINING WHAT CAN OR SHOULD BE DONE TO ERADICATE AND PREVENT THE SPREAD OF AIDS

APRIL 16, 1986

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CONTENTS

STATEMENTS

Wednesday, April 16, 1986

Page

American Hospital Association, prepared statement 312

American Medical Association, prepared statement 305

Clinton, Dr. J. Jarrett, Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance, Department of Defense 133
  Prepared statement 136

Cranston, Hon. Alan, a U.S. Senator from the State of California, prepared statement 302

Fineberg, Dr. Harvey V., dean, Harvard School of Public Health; Dr. Anne Scitovsky, chief, Health Economics Department, Palo Alto Medical Foundation and Research Institute, and Barbara Lautzenheiser, consultant, Trans America Occidental Life Insurance Co 151
  Prepared statement of:
    Dr. Fineberg 154
    Dr. Scitovsky 163
    Ms. Lautzenheiser 194

Grassley, Hon. Charles E., a U.S. Senator from the State of Iowa, prepared statement 3

Kennedy, Hon. Edward M., a U.S. Senator from the State of Massachusetts, prepared statement 5

MacDonald, Dr. Donald Ian, Acting Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, accompanied by Dr. Walter Dowdle, Acting AIDS Coordinator, PHS; Dr. Henry Meyer, Food and Drug Administration; Dr. Anthony Fauci, National Institutes of Health; Dr. Donald Hopkins, Centers for Disease Control; Dr. Frederick Goodwin, Alcohol, Drug Abuse and Mental Health Administration; Dr. Audrey Manley, Health Resources and Services Administration, and Shellie Lengel, Office of Public Affairs, PHS 76
  Prepared statement 79

Pell, Hon. Claiborne, a U.S. Senator from the State of Rhode Island, prepared statement 4

Smith, Nathan, immediate past president, National Hemophilia Foundation; Jeffrey Levi, director or governmental and political affairs, National Gay and Lesbian Task Force, Washington, DC; and Helen G. Kushnick, member of the board of directors, American Foundation for AIDS Research 6
  Prepared statement of:
    Mr. Smith 11
    Mr. Levi 22
    Mrs. Kushnick 43

ADDITIONAL MATERIAL

Questions and answers:

  Responses by the administration to questions by Senator Hatch 269
  Responses by the administration to questions by Senator Kennedy 286

Articles, publications, etc.:

  To Live Until We Say Goodbye, by Elisabeth Kubler-Ross 55
  Inside the Billion-Dollar Business of Blood, by Andrea Rock, March 1986 56
  Public Health Service Plan for the Prevention and Control of AIDS and the AIDS Virus, report of the Coolfont Planning Conference, June 4 to 6, 1986 318

Page

Articles, publications, etc.—Continued

The Nonprofit Sector's Responses to the AIDS Epidemic: Community-Based Services in San Francisco 335

Questions and answers:

Responses of Mr. Levi to questions submitted by Senators Hatch and Kennedy 31
Responses of Mrs. Kushnick to questions submitted by Senators Hatch and Kennedy 51
Responses of Dr. Clinton to questions submitted by Senators Hatch and Kennedy 141
Responses of Dr. Scitovsky to questions submitted by Senators Hatch and Kennedy 170
Responses of Ms. Lautzenheiser to questions submitted by Senators Hatch and Kennedy 197

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

WEDNESDAY, APRIL 16, 1986

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:52 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin Hatch (chairman) presiding.

Present: Senators Hatch, Kennedy, Metzenbaum, Simon, Pell, and Nickles.

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. Ladies and gentlemen, as we come together today, America is experiencing an epidemic—an epidemic of fear.

Like most fears, this epidemic is caused not by something we know—but by something we do not know about—the disease we call Acquired Immune Deficiency Syndrome, AIDS.

But I am not sure it would be an overstatement to say that we have more to fear from this hysteria about AIDS than we have to fear from AIDS itself.

These fears persist even though the scientific community has made a great deal of progress so far in its research on AIDS. In the very short time since AIDS was first recognized in 1981, we have learned what causes AIDS and we have developed tests to diagnose it. Drugs are being devised to combat it and a vaccine to prevent it.

It appears the AIDS virus is not casually transmitted, but instead requires the exchange of bodily fluids or the intake of blood products. We know the disease has mostly limited itself to high-risk groups such as male homosexuals, intravenous drug abusers and recipients of blood products. And there is reason to believe that many individuals in the high-risk categories can greatly reduce their risk of contacting or spreading AIDS.

Many experts agree with Dr. June Osborn, a public health scholar, in her characterization of the scientific community's response to AIDS. Dr. Osborn says: "I think it is safe to say that humankind has never responded so quickly and thus far so effectively to a novel medical challenge."

I agree that the scientific community has done much to allay fears about this disease. But in its satisfaction about its progress so far, will the scientific community grant an air of finality to what are really just preliminary conclusions? Will the Federal Government give short shrift to some real concerns about AIDS among the public-at-large?

We must not forget that we are still talking about a disease here that in our experience has been 100 percent fatal, and which is growing exponentially in terms of people afflicted. More than 16,000 cases had been identified by the beginning of this year, and this number is expected to double by the end of this year.

And we are still talking about a disease which is beginning to spread beyond the high-risk groups; 4.6 percent of AIDS cases now fall outside these groups.

Instead of patting ourselves on the back and dismissing those who still harbor fear and doubts as know-nothings, we must recognize that what we have accomplished so far was the easy part. What we do not know about AIDS still dwarfs what we do know. We must use our early successes to build momentum so that we can tackle the tough and controversial questions that feed our fears.

Take the Federal Government's continuing role in AIDS research. Some argue that the Government did too little too late, but there is no question that some of the trail-blazing research was sponsored by the Government and that this support still continues.

But I am concerned that we have not examined the other side of the coin. The total Government investment in AIDS research, control programs and public education since 1981 now approaches half a billion dollars—a tremendous sum, considering our fiscal limitations.

Is this money getting us closer to a cure or vaccine? Is it being invested wisely toward that goal? And when will we see a cure or a vaccine, and will they work? When will we get better diagnostic tests?

is controversy over who did what, first standing in the way of the kind of collaboration that could produce concrete benefit for patients?

Then there is the role of the Food and Drug Administration. We have heard about the fast track for AIDS research efforts and promising reports on products. But when will these products begin to reach the market?

We must ask who will bear the future financial costs to our society, including the estimated $15 billion just for treatment of AIDS.

By far the most painful and frightening questions about AIDS deal with the possibility of contagion. What can or should be done to prevent the spread of AIDS beyond the risk groups?

What guidance can we give employers who fear liability from sick employees exposing fellow workers or the general public to AIDS? All of us feel bad for the innocent young victims of AIDS, but how can we reassure the parents of other children at school?

How good are current blood screening tests? Are better tests on the way? And how well are we informing potential donors or recipients?

In the last few minutes, I have asked a good many tough and controversial questions. But we are not here to call anyone on the carpet or to make any heads roll. We do not want to point fingers at any group, to limit anyone's rights or liberties, and especially, to give rise to any new fears.

And most of all, we do not want to label AIDS as a health issue, or a science or research issue, or a gay rights issue, or a Government spending issue, or a liability issue. Because what we are really dealing with here is not issues but people—people who are sick, people who are scared to death, people who are scarred by their experiences in dealing with this epidemic of fear.

In our hearings today and in following hearings, I hope we can take stock of where we are, both in the Government and in the private sector, and in terms of learning about AIDS and fighting its spread, and eventually in curing it.

The American public has a right to be free from unwarranted fear about AIDS. And I believe that in the process of shedding a little light on a mysterious and frightening subject, we will also go a long way toward fighting this epidemic of fear that is surrounding AIDS—and getting on with the process of wiping AIDS itself off the face of the Earth once and for all.

We hope we are able to get that ultimately accomplished. To that end, I appreciate the efforts of all of our witnesses here with us today to help us understand more about this very, very serious public health problem.

At this point we will receive for the record statements by Senators Grassley and Pell.

[The prepared statements of Senators Grassley and Pell follow:]

Prepared Statement of Senator Chuck Grassley

Thank you, Mr. Chairman, it is certainly appropriate that our Committee is examining the Department's activities with respect to the AIDS epidemic, given that making progress against this disease is the Department's highest public health priority, at least according to the testimony of several of our administration witnesses today, and also according to the new Secretary of Health and Human Services in his testimony before the Appropriations Committee last month. As the oversight committee on this issue, we need to satisfy ourselves that the Department's efforts to make progress against the AIDS epidemic are well thought out and efficiently conducted.

AIDS is a devastating disease which presents us with the closest thing to a public health emergency that we have faced in many years. Not only is this disease devastating to those who develop it in its "full-blown," active stage, but it has been spreading at a truly awesome rate. As I understand it, the number of these "full-blown", active cases has doubled in the last year, to about 18,000. In addition, we now have around one million people who have been infected, but who are not symptomatic, although, according to conservative estimates, some 10 percent of them will develop the disease in its active stage within three years. It appears that these people are capable of spreading the disease. Furthermore, there does seem to be some possibility that the disease is spreading into the heterosexual community. It certainly seems appropriate to me that the Department has designated progress against AIDS as its highest public health priority.

At the present time, it appears that the development of a cure for this disease is still some time off. In the meantime, education and information efforts with respect to risk factors associated with the disease and personal behavior which contribute to spreading it seem to hold great promise for limiting the spread of the disease and containing it. This is indicated by a substantial reduction in the incidence of sexually transmitted diseases among the main affected population. I hope that we will discuss the Department's educational efforts and how they might be improved. I feel sure that they can be improved, given that there seems to be fairly widespread lack of confidence among the general public in the assurances with respect to AIDS emanating from official and responsible sources.

That is all I want to say at this time, Mr. Chairman. I look forward to hearing or reading the testimony of our witnesses.

PREPARED STATEMENT OF SENATOR CLAIBORNE PELL

Thank you for the opportunity to discuss one of our nation's foremost health priorities. The importance of such dialogue cannot be overstated as AIDS is now understood to be much more of a universal concern than originally anticipated.

It appears that although AIDS is a serious health problem, much remains to be explored in this area. Of course, research in terms of a cure or vaccine is vital. However, it is also quite clear that there is an equal need for further education of both high risk groups as well as the general public. There is a great deal to be done to clear up the many misconceptions that exist about AIDS which may be standing in the way of progress.

AIDS is a problem that needs to be addressed with appropriate seriousness—not paranoia or hysteria. Discussion such as this is necessary for further cooperation, which is evidently a great necessity.

The **CHAIRMAN**. With that, we will turn to Senator Metzenbaum.

OPENING STATEMENT OF SENATOR METZENBAUM

Senator **METZENBAUM**. Thank you, Mr. Chairman.

I am very pleased that we are having this hearing today. I think it is frankly overdue. But I think you have assembled an excellent group of witnesses.

We have a disease that has killed nearly 10,000 Americans, 150 of them children. And the health care costs in connection with the problem have exceeded $1 billion.

The Government's Center for Disease Control says AIDS is worse than anything mankind has seen before. And in the face of that, the President's fiscal 1987 budget calls for a recision of $40 million in fiscal year 1986 AIDS funding, and a $20 million cut for fiscal year 1987. Gramm-Rudman will cut $11 million in AIDS spending this year alone.

Mr. Chairman, subsequent to the meeting I will ask you to join and to lead all of us on the Labor and Human Resources Committee in letting the administration know that this is a false kind of economy and that our Nation will end up paying the price.

As a matter of fact, Dr. MacDonald in his testimony says that it will take 14 years to bring this disease under control. Well, frankly, in 14 years, the exponential expansion of this disease would be so critical and so frightening to all of America that we cannot, we just cannot afford to let it happen. And I think we all ought to join together in a bipartisan approach and let the administration know that this kind of a recision is bound to cost us millions, perhaps billions, of dollars in the future. Putting the financial costs aside it will cost us an untold number of lives.

From the administration, we are getting mixed signals on AIDS. Hopefully, this hearing will send a clear signal to the American people, who are rightfully concerned about the spread of this devastating disease. We must be able to show the American people that we are doing all that we possibly can to find a cure to bring AIDS under control. We must also provide them with clear, accurate information from the scientific community. It is the only antidote to hysteria, and I think this committee's hearing today may help somewhat along that line.

I am happy to join you today. I will not be able to stay the entire morning, due to other commitments that just cannot be broken; but my failure to remain will not indicate any lack of interest or lack of commitment, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Metzenbaum.

Senator Kennedy.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. Thank you very much, Mr. Chairman.

I too want to say how much I appreciate the fact that we are holding this hearing this morning here in the Senate on a public health issue, a health issue of enormous importance and consequence for our country, and I think in an important way, really, for the world. I think those of us on this committee, particularly those who have been involved in health issues and in the AIDS issue, are very much aware of the rising incidence of AIDS which has been reported to the Centers for Disease Control. The number is increasing. This does not even measure the dramatic number of reported cases of AIDS-related complex, which is a problem of enormous importance and has to draw our attention as well. And then we know that those who have been infected and carry the antibody is 50 times as large as the reported number of cases.

So the flow line, Mr. Chairman, and members of this committee, of those who are going to be affected or impacted is dramatic. We are all familiar with the figures that, by the early 1990's, we will lose the total number of individuals lost in the Vietnam War, unless we are able to see a very significant breakthrough. AIDS has become the principal cause of death among young men in our society, in many of our largest cities. Even when we talk about the statistics, we do not measure the anxiety, the suffering, the confusion which has taken place among many in our society as well.

So it is important that we focus in and find ways that we in the Congress and in the Senate can help meet our responsibility to our fellow citizens.

I think before we hear our witnesses, we ought to recognize that there has been some important good news last week, with the announcement that the smallpox vaccine may be a purveyor of an effective immunity to AIDS, and that this vaccine will soon be tested in primates. We will be interested to find out from the FDA and others about what kinds of prospects and what kind of hope this offers for the future

I believe that we have five major areas on which we have to focus. One is the spread of AIDS and how that must be prevented. The research toward a cure must continue, and it must continue fullspeed ahead. We need humane and accessible medical services that must be available to all who are ill. The blood supply must be monitored, and it must be protected in our society. And the anxiety-provoking ethical and legal issues certainly must be addressed.

So I would hope that we could gain additional information in those and other areas from our witnesses from whom we can benefit. I welcome the opportunity to hear from them today.

I thank the Chairman.

The CHAIRMAN. Thank you, Senator Kennedy.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR EDWARD M. KENNEDY

Acquired Immune Deficiency Syndrome is one of the most serious health epidemics in our history. By the year 1990, it is estimated that 76,000 Americans will have contracted this disease. Every 24 hours, another eight people die of AIDS and 190 people are newly infected. By the early 1990's, this disease will have claimed more lives than the Vietnam War.

Though considerable resources have already been allocated to the fight against AIDS, much greater efforts and commitments are needed. A cure must be found. A vaccine must be developed. Further spread must be stopped. We must treat the sick with humaneness and compassion.

Today, along with Senators Moynihan, Simon, Kerry, Dodd, Matsunaga, and Metzenbaum, I am introducing the Acquired Immune Deficiency Syndrome Counseling, Education and Services Act of 1986. The primary purpose of this bill is to disseminate accurate knowledge about the disease. It will support counseling (including mental health counseling) of individuals who are antibody-positive to the AIDS virus, information dissemination among high risk groups to reduce the risk of further transmission, and education for those whose work is likely to bring them into contact with AIDS victims.

Second, it will support the establishment of cost-effective networks of outpatient medical services for AIDS patients. This program will allow the 23 cities that have more than 100 cases of AIDS and 1,000 cases of AIDS Related Complex to organize coordinated services, including community-based and home care services as alternatives to long-term hospitalization.

Third, it will establish a coordinating committee at The National Institutes of Health to guide the crucial national research effort in the months and years ahead.

Facing up to this national epidemic will require far greater effort than we have made in the past. This bill can help us meet the challenge with rationality, dignity, and hope. I urge the Congress to support it.

The CHAIRMAN. Our first panel of witnesses is composed of three individuals who have confronted AIDS, either through personal illness or through the illness of a family member of friends. They know what AIDS can do and what fear of AIDS can do. They will share with us these experiences, and in addition, I hope they will share with us their ideas on how we can improve the lot of future AIDS patients.

Our witnesses are: Mr. Nathan Smith, immediate past president of the National Hemophilia Foundation; Mr. Jeffrey Levi, director of government and political affairs of the National Gay and Lesbian Task Force, and Mrs. Helen Kushnick, of the board of directors of the American Foundation for AIDS research.

I want to thank all of you for coming here today. I look forward to hearing your testimony in this very important hearing. We appreciate the efforts that you are making: They are efforts that will be beneficial for people throughout our society.

Mr. Smith, we will begin with you. We are happy to welcome you here.

STATEMENT OF NATHAN SMITH, IMMEDIATE PAST PRESIDENT, NATIONAL HEMOPHILIA FOUNDATION; JEFFREY LEVI, DIRECTOR OF GOVERNMENTAL AND POLITICAL AFFAIRS, NATIONAL GAY AND LESBIAN TASK FORCE, WASHINGTON, DC, AND HELEN G. KUSHNICK, MEMBER OF THE BOARD OF DIRECTORS, AMERICAN FOUNDATION FOR AIDS RESEARCH

Mr. SMITH. My name is Nathan Smith, and I live in Fort Worth, TX. I am currently employed with the Equitable Life Insurance Society in a managerial position at a regional computer center. I am also in the final month of preparation for an M.B.A. degree in health services administration. Between 1982 and 1984, I served as president of the National Hemophilia Foundation.

My wife, Linda, and my six children are former residents of Chicago and Salt Lake City and various places in Texas, including Houston, and now Fort Worth.

I was born with severe hemophilia, and as a result I have been dependent upon blood products needed to control bleeding episodes that I have experienced nearly 2,000 times in my life. But blood products that have been used in that treatment have exposed me to over 2 million donors. That means 2 million people who have had various types of viral diseases have transmitted their plasma into products that have been concentrated and have come into contact with me. That is how I obtained my exposure to AIDS.

Nevertheless, despite this vulnerability, many of us are grateful for the scientific technology that has allowed hemophilia to be a controllable disease.

But in 1982 we learned about a new disease, Acquired Immune Deficiency Syndrome, that was soon to become the most serious challenge to all of the progress we have made. In November 1985, I was diagnosed as having AIDS.

I would like to start off by sharing some of my personal experiences related to AIDS, and then I would like to review the impact of AIDS on the hemophilia community, in reciting the progress that has been made and yet the problems that still remain.

Six months before I was diagnosed, I had developed a case of oral candidiasis, otherwise known as thrush. Although I was aware that this was one of the symptoms associated with AIDS, I was not too concerned because I was then receiving antibiotics for another condition, and antibiotic therapy often produces the same results.

But in 1985, in August, I began to be extremely fatigued and to have difficulty with breathing, shortness of breath, and by the time November arrived, after several consultations with doctors, I found that I was in requirement of hospitalization to verify whether I had a serious complication resulting from AIDS, a complication known and diagnosed as Pneumocystis Carinii Pneumonia, or PCP for short.

At this time, I knew after the diagnosis that I in fact had contracted AIDS. AIDS cannot be measured in the same way as other diseases, but you can observe the result of AIDS, which are the infectious diseases.

My initial reaction was that of relief, believe it or not, and that was because I had been worrying about AIDS for 3 months. Now, I did not have to worry. I was relieved because now I had an opportunity to set in motion some plans that could be a little more concrete than worrying about the hovering cloud of AIDS over the horizon.

Several things occurred as a result. I immediately discovered what it is like to live in a foreign world. There in the hospital within the first few days, I was treated as if I had an extremely communicable disease. People would put gloves on and would put masks on and would put gowns on in order to talk with me. I somehow could not escape the feeling that regardless of the risks, the psychological damage to the patient is substantial when he is seen as a modern leper. I really felt difficulty with this process until about two-thirds of the way through the hospital stay. After doctors had confirmed that I was not contagious in any real sense, they took those restrictions off. You cannot express what it is like to know when they are bringing a plate of food in for you that it is on paper that they will throw away because they do not want to have to deal with the problems of washing it, how that changes your attitude toward your future, because you suddenly have a very different kind of lifestyle.

As a result of this, we have to carry on in our family is a kind of continuing education process. I love my children. They come and kiss me good night. And yet my 9-year-old daughter, when she came in last week and bent over to kiss me goodnight before she went to bed, straightened up afterwards, put her hand to the back of her mouth and wiped it off, because she is aware that AIDS is a problem. And I have to go through a lot of counseling to tell her, look, it is not going to be transmitted that way. But how does it make you feel when you have something like that occur in your own family? You have difficulty in making some of these adjustments that are required.

It is not because the AIDS is a transmissible disease; none of my family have any prospect or any symptoms of the disease, but they have been reading and they have been hearing, and they go to school with friends who tell them all kinds of fairy tales.

One of the things I discovered was that there was a tremendous outpouring of support. Just last week, I received a letter from a lady that I had had some slight association with a few years ago, and she said that she had just heard that I was an AIDS patient, and she said she was encouraging me in a number of things. She said, "I pray in the hope that a cure will happen soon enough to enable you to triumph over this. Have you considered writing about this situation, sharing your thoughts and feelings with the hemophilic community, perhaps the public at-large?" She did not know I was coming here, but I trust that I can at least now begin to pay back some of those kind well-wishings that I have had while I have been in the hospital and since my diagnosis.

I have noted too that preparations in life take a little different intensity when you know that that life may be short. Somehow every day becomes even more meaningful. Most of us saw a rainstorm today. I thought it was great. I love rain. But I love weather—I just love to see the sun rise every day.

I have gone beyond the questions which naturally occur, which are: Why me? Why now? Why at all? Those questions are not productive. I think better, the question is: How am I preparing myself for my future, and how am I preparing my family? What am I doing about it? There are certain risks we all take, and AIDS is one of those unfortunate ones that I have been exposed to because of my hemophilia.

But asking why is not necessarily going to solve my problems.

I feel a greater degree of kinship toward many who suffer from incurable disease, and I believe that where there is life, there continues to be hope.

A great deal of the support that I feel for my attitude at this point in my life and my family is coming from my church, and I think others could say the same, whatever their persuasion.

On the stigma of AIDS, I can recount a couple of instances. One of them, when I was in Houston after being diagnosed, my family came down to visit and stayed at a friend's house. Then, subsequently, I was released from the hospital to return to Fort Worth. We stopped by our friend's house, and our friend, who watches a number of children, said that she had talked with some of the families and asked if it would be all right if I could come in and visit. And one of the mothers, who was a high school teacher and who should know better—a science teacher, at that—said no, she was going to take her child out of this health environment if I so much as set foot through the door. So I sat in the car while my family went inside and visited with our friends, and felt at first hand again, the exposure of ignorance—not because the disease was likely to be transmitted—there is no chance of that—but because someone had read or suspicioned something that was not correct and changed their behavior and forced others to change their behavior as a result.

There is too much of this, I think, still happening and a lot of misinformation about the disease.

At home, I eat off the same plates as my family, we use the same bathroom facilities, I continue to hug and kiss my children. But with respect to my wife, clearly, we know that it is a sexually-transmitted disease, and I follow the precautions recommended by the CDC in order to avoid transmission of the disease. And fortunately, my wife is not HTLV-III positive, and we are reasonably sure that she has not been exposed to the disease.

Now, there are many things I could say about hemophilia, but I have included them in the statement, and I will not take the time to read them. But I do want to emphasize two things of importance. One of them is the outstanding cooperation of the Federal Government thus far with the National Hemophilia Foundation, especially through the Centers for Disease Control. I think in many ways this collaborative effort has been a model for how the Federal Government and the private sector can work together to gain information, to disseminate proper data, as well as to collaborate on the research efforts. Thus far, a great deal has been accomplished, and I would say that in this respect, the Federal Government and CDC are to be congratulated for their efforts thus far.

The second part is that the disease is a difficult one and obviously will require a great deal of long-term care and counseling. I do not know that we have factored into our considerations how much it is going to cost for future generations of wives, children, employers, to understand that AIDS has certain implications which they may need to be counseled about.

We talk about the immediate transfusion costs, we talk about the immediate treatment costs, but we do not talk about long-term social costs. My wife is in counseling because she, of course, has a big burden—how to deal with the problems that will be created as my disease unfolds. And I cannot assess the impact because I may not be here to deal with that impact. But somebody has to. And I hope, for our sakes, that through the Government's resources, methods can be found to provide that.

I was very hopeful when I saw the bill that is to be introduced, and I believe that will do a lot toward helping this.

I remember back in early July 1982, when Dr. Bruce Evatt, of the Centers for Disease Control, contacted the NHF about AIDS and hemophilia. I remember the steps that have been taken to survey all the hemophiliacs in the country to find out what they thought and whether they had any exposure to the disease. Since that day in July 1982, the progress that has been made and the challenges that are now being addressed are the results of this model that I have talked about, which is really remarkable. The pooling of resources, combined with volunteer support of physicians, nurses, social workers, and other health professionals from 100 treatment centers around the country are providing us with a unified mission to learn more about the etiology of AIDS and how it is spread among people with hemophilia.

I am most gratetul, as are those affected by hemophilia throughout the country, for the support we have received from Congress and the commitments you have made by having this hearing.

But we have a long way to go as the number of afflicted AIDS cases doubles every 13 or 14 months. While I maintain my hope of surviving since I was diagnosed with AIDS, it has become increasingly difficult for me to look to the future in a personal way. If my future passes before a cure is found for AIDS, I want you to know that it is reassuring to me, in a very deep and personal way, to know that you have significantly helped to spark a national commitment to help find a cure, so that the many futures of others will not be shortchanged in the years ahead.

Thank you.

The CHAIRMAN. Thank you very much, Mr. Smith. We appreciate your testimony. It is very poignant.

[The prepared statement of Mr. Smith follows:]

THE NATIONAL
HEMOPHILIA FOUNDATION

TESTIMONY SUBMITTED TO
THE U.S. SENATE LABOR & HUMAN RESOURCES COMMITTEE

AIDS AND HEMOPHILIA

STATEMENT BY: NATHAN SMITH
FORT WORTH, TEXAS

APRIL 16, 1986

THE SOHO BLDG. • 110 GREENE ST. • RM. 406 • NEW YORK, NY 10012 • (212) 219-8180

My name is Nathan Smith and I live in Fort Worth, Texas. I am currently employed with The Equitable Life Assurance Society in a managerial position at a regional computer center, and I am also in the final month of preparation for my MBA degree at the University of Dallas. Between 1982 and 1984 I served as president of The National Hemophilia Foundation. My wife Linda, whom I love dearly, has given birth to my 6 children, ages 4-15.

I was born with severe hemophilia and, as a result, I have been dependent upon blood products needed to control bleeding episodes that I have experienced nearly 2000 times during the course of my life. This means that I probably used blood products that have exposed me to over 2 million blood or plasma donors during the past 44 years. Being vulnerable to diseases that have the potential for being transmitted through blood products has always been a fact of life for me, as well as other people with hemophilia throughout the United States. Yet, despite this vulnerability, scientific advances now enable us to live normal, independent and productive lives.

Then, in 1982, we learned of a new disease, acquired immune deficiency syndrome (AIDS) that was soon to become the most serious challenge to all of the progress we have made. In November of 1985, I was diagnosed with AIDS.

I would like to start off by sharing some of my personal experiences related to AIDS, and then I would like to review the impact of AIDS on the hemophilia community, revealing the progress that has been made and the serious problems that remain.

Six months before I was diagnosed, I had developed a case of oral candidiasis, otherwise known as thrush. Although I was aware that this was one of the symptoms associated with AIDS, I was not too concerned because I was also receiving antibiotics which often lead to this type of infection. My worst fears surfaced in August of 1985, when I began to feel severe fatigue, which peaked in November.

At this point, I went to M. D. Anderson Hospital in Houston for evaluation and, in late November, I was diagnosed with Pneumocystis Carinii Pneumonia (PCP). At that time I knew that this meant I had contracted AIDS through the blood products that I had used to treat my bleeding episodes. My initial reaction was that of relief, as I had suspected this for a number of months. I was relieved because this provided me with an opportunity to set some plans in motion about my life and for my family. During the five months since I was diagnosed, my entire perception of life has been thrust into a totally different perspective. I know now, first hand, what it is like to live with AIDS.

1. I was truly surprised by the outpouring of sympathy and affection from people in NHF, acquaintances and others who I never would have known would have been aware of what my problems were. The conclusion I draw from this is that I am not in the battle alone.

2. My perceptions of life, the joys and the intensity of it are much deeper than before. The conclusion I drew from that is that life itself is the type of ultimate test we all have to surmount, and the ultimate problem that is to be surmounted is dealing with the prospect of one's own death.

3. I have gone beyond the questions which naturally occur which are, "Why me?", "Why now?", and "Why at all?" Instead, I ask myself, "How am I prepared for my family, as well as myself, and what is available to help me?"

4. I feel a greater degree of kinship toward the many who suffer from incurable diseases and I believe that, where there is life there continues to be hope.

5. A great deal of the support that I feel for my circumstances comes from the structure that is provided by my religion. This has helped me to find peace during this very difficult period of my life.

On several occasions I have experienced the stigma of having AIDS, but it is difficult for me to fully assess this stigma, as the reactions of others are often conveyed through whispers and the person involved never really knows. But overall, I have found members of my family and friends, as well as colleagues at my workplace to be very sensitive to my condition. They are supportive and they continue to be close to me, despite any fears that they may have had.

At home, I eat off the same plates as my family; we use the same bathroom facilities; I continue to hug and kiss my children. Fortunately, we know there are not any risks of spreading AIDS through casual contact. Of course, with respect to intimate contact with my wife, it has become necessary for me to use the precautionary measures that are available to prevent the spread of the disease through sexual contact. But this adjustment is secondary to the underlying psychological adjustments that are needed to face the overall impact of the disease on myself and my family.

Now I would like to shift the focus of this presentation from myself to the overall impact of AIDS and HTLV-III infection on the hemophilia community.

HEMOPHILIA - WHAT IT IS

Hemophilia is a lifelong, hereditary blood clotting disorder which affects males almost exclusively. The blood of a person with hemophilia does not clot due to the inactivity of a plasma protein in the blood. We may experience uncontrolled, painful bleeding. Without adequate treatment, chronic joint bleeding results in progressive joint damage and crippling.

IMPACT OF AIDS

Since the early 1970's, the advances in hemophilia care have enabled people with hemophilia, for the first time in history, to lead nearly normal, full and productive lives. (See attached July 1984 article from the American Journal of Public Health.) Now we are faced with the frightening specter of AIDS and HTLV-III infection. Because of the way in which therapeutic blood products are prepared, a person with severe hemophilia may be exposed to as many as 100,000 blood donors per year. Blood clotting factor, the source of our newly found freedom from pain and disability, has changed overnight from a life sustaining substance to a possible threat to our survival. The most recent data reveal:

- one in every 135 individuals with hemophilia has contracted AIDS (for those with severe hemophilia, the rate is one in 75);
- it is now known that 90% of persons with severe hemophilia have been exposed to the HTLV-III virus;
- two wives of men with hemophilia have contracted AIDS;
- it is estimated that, unless preventive measures are utilized, 1 to 5% of sexual partners of people with hemophilia will convert to HTLV-III positive status each year;
- one child of a man with hemophilia has contracted AIDS; and
- an increased number of AIDS cases has been reported in patients with mild and moderate hemophilia.

A year ago, the fear of AIDS was confined to the person with hemophilia. Now,. with the threat of heterosexual transmission and the potential of neonatal cases of AIDS in families affected by hemophilia, it is apparent that the risk of transmission to family members is real, when intimate sexual contact is involved.

I have now reached the point where it is important to recommend risk reduction measures be considered in intimate relations. In order to reduce the transmission of AIDS in the hemophilia community, it is important that accurate information be disseminated rapidly through training, education and counselling. It is equally important to dispel inaccurate information about AIDS, HTLV-III infection and hemophilia.

PROGRESS IN REDUCING THE RISK OF AIDS AMONG PEOPLE WITH HEMOPHILIA

As a result of enormous collaborative efforts between the public and private sectors, there has been substantial progress in reducing the risk of AIDS among patients and families affected by hemophilia:

- education/screening of donors is universally applied among volunteer and commercial blood collection organizations;
- HTLV-III antibody testing is now applied to all donated blood and plasma;
- HTLV-III virus inactivation methods are now universally applied in the preparation of clotting factor concentrates; and
- DDAVP (a synthetic analog that stimulates the release of stored Factor VIII) for persons with mild and moderate hemophilia and von Willebrand's disease is, in most instances, substituted as an alternative to human source plasma products.

Based on these advances, it appears that the steps detailed above have led to blood products for treatment of hemophilia that are virtually free of HTLV-III contamination.

Concern remains, however, about the large percentage of people with hemophilia who are antibody positive and the potential for the transmission of AIDS and/or HTLV-III infection to their sexual partners. Concern exists regarding the importance of people with hemophilia maintaining their treatment of bleeding episodes when medically indicated, despite their fear of AIDS. Special attention is also needed to address AIDS-related stress that is experienced by patients and families. But, most important of all, how many of the 90% of the people with severe hemophilia who are HTLV-III positive will succumb to AIDS?

The National Hemophilia Foundation has identified the following major challenges ahead for the hemophilia community with respect to AIDS and HTLV-III infection.

1. The most important goal is to promote research into methods of treating and curing all those with AIDS, as well as those who are infected with HTLV-III.

2. There is great importance in reinforcing public confidence that AIDS is not spread through casual contact. Many people with hemophilia fear the risks of discrimination in the workplace and school. There are excellent data that document the fact that AIDS is not being spread through casual contact (see attached CDC presentation - October 11, 1985). Over the last several months, over six hundred household contacts (non-sexual) of people with hemophilia have been tested, and every one of them is HTLV-III negative.

3. Major efforts are underway to reduce the risk of heterosexual and perinatal transmission of AIDS and HTLV-III infection.

4. It is said that, "To an ill patient, no news is not good news but, rather, an invitation to fear." This is so true with respect to AIDS, and ongoing efforts are being maintained to provide accurate and updated information about AIDS and HTLV-III infection and hemophilia to patients, families and health professionals.

5. Some patients with hemophilia curtailed their treatment of bleeding episodes when medically indicated. For these people, the fear of AIDS may prove to be a greater risk than AIDS itself because the life and health of people with hemophilia depend upon the appropriate use of blood products. The importance of treating needs to be reinforced at all times during this difficult period.

6. Ongoing attention is needed to strengthen psychosocial support to individuals and families affected by hemophilia (this includes those who have developed AIDS as well as those who have not).

7. The rapid development of safer therapeutic blood products needs to be encouraged. Even without AIDS, the potential of disease transmission is always present for people with hemophilia.

I remember back in early July of 1982 when Dr. Bruce Evatt of the Centers for Disease Control contacted The National Hemophilia Foundation to inform us that three people with hemophilia, with no other risk factors, had contracted AIDS. That marked the beginning of an excellent relationship between The National Hemophilia Foundation and the Centers for Disease Control that continues to this very day. Other leaders in the National Institutes of Health and the Food and Drug Administration have worked closely with The National Hemophilia Foundation in the most constructive way to help us during this terrible AIDS crisis. Congress, both Republicans and Democrats, have been supportive and sincerely sensitive to the problems we are facing.

Since that day in July of 1982, the progress that has been made and the challenges that are now being addressed are the results of a remarkable "model" of private and public sector cooperation. Ever since that time, NHF and numerous government agencies have pooled their resources, combined with the volunteer support of physicians, nurses, social workers, and other health professionals from 170 treatment centers around the country with a unified mission to learn more about the etiology of AIDS and how it is spread among people with hemophilia. I am most grateful, as are those affected by hemophilia throughout the country, for the support we have received from Congress and the commitment you have demonstrated by holding this hearing. But we have a long way to go, as the number afflicted by AIDS continues to double every thirteen or fourteen months. While I maintain my hope of surviving, since I was diagnosed with AIDS, it has become increasingly difficult for me to look to the future in a personal way. If my future passes before a cure is found for AIDS, I want you to know that it is reassuring to me in a very deep and personal way to know that you have significantly helped to spark a national commitment to help find a cure so that the many "futures" of others will not be shortchanged in the years ahead.

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PUBLIC HEALTH BRIEFS

The Benefits of Comprehensive Care of Hemophilia: A Five-Year Study of Outcomes

PETER S. SMITH, MD, PETER H. LEVINE, MD,
AND THE DIRECTORS OF ELEVEN PARTICIPATING HEMOPHILIA CENTERS*

Abstract: Eleven of 22 federally funded Comprehensive Hemophilia Centers have collected data on outcomes, before and after five years of this program's existence. Improved health, decreased hospitalization, decreased absenteeism, and a decrease in the unemployment rate from 36 per cent to 13 per cent were accompanied by decreased costs of care. In this model of a chronic handicapping illness, the early application of comprehensive care is preferable to the previous emphasis on end-stage rehabilitative efforts. (*Am J Public Health* 1984; 74:616–617.)

Introduction

About one in 5,000 males has hemophilia, congenitally lacking factor VIII (Hemophilia A or Classical Hemophilia) or factor IX (Hemophilia B or Christmas Disease). The inadequately treated hemophiliac can expect a shortened and anxiety-ridden life of pain, confinement, progressive crippling, and restricted opportunities.[1,2]

In 1975, Section 1131 of the Public Health Service Act established and funded a network of Hemophilia Diagnostic and Treatment Centers throughout the United States.[3] There are now 22 such regional centers providing comprehensive services to the hemophiliacs in their catchment areas. The present report is an analysis of health care outcomes and costs from 11 centers which voluntarily agreed to compare data on five full years of activity with available information from the year before inception of the program.

Description of the Centers

The minimum services provided by each center were:

- A coagulation laboratory of recognized high standards;
- A blood bank providing all of the blood components needed by hemophiliacs;
- A multidisciplinary hemophilia care team including a hematologist, an internist, a pediatrician, an orthopedic surgeon, a physical therapist, a dentist, a social worker, and a registered nurse;
- Formal linkages with mental health, genetic counseling, and rehabilitative services;
- A training course in self-therapy (home care) and updated hemophilia concepts for patients and family members;
- An outreach program to enable every hemophiliac within the area served to receive services of the program.

Every effort was made to use all existing resources for funding hemophilia treatment and, in many cases, centers worked closely with third party payers, such as Blue Cross/Blue Shield, to develop private funding for services.

Within the confines of 22 defined geographical areas in the United States, liaisons were established with any already existing state hemophilia programs. In sectors lacking any such programs, satellite or affiliate centers were set up or organized by staff of the primary federally funded centers. Currently we estimate about one-half of the hemophiliacs in the United States have access to such programs.[1]

Methods

Although no funding was available for data collection, one-half of the centers agreed to participate, representing a good cross section of the whole network in terms of geographic, socioeconomic, and age distributions. A standardized data collection form was developed.* Data were collected and tabulated at each center by the hemophilia nurse coordinator, the social worker, or both, and reviewed by the director. Overall costs of health care were obtained from the records each center kept of its blood product consumption for the year, and account for almost all of the cost of treatment.[4] The average costs of care per patient per year was calculated as previously described.[4] In addition, each patient was asked to estimate his out-of-pocket treatment expenses for the year.

Results

During the year prior to federal funding, the 11 participating centers and their affiliates saw 2,112 patients. Five years later (fiscal 1981), more than twice as many patients (4,742) were receiving comprehensive care through the centers. Eighty-six per cent of the patients served by the centers in 1981 had factor VIII deficiency, while 14 per cent had factor IX deficiency; 67 per cent had the severe form of the disease and 33 per cent were moderate or mild hemophiliacs, using the standard criteria described elsewhere.[4]

While initially only 514 patients were knowledgeable and skilled enough to treat themselves with appropriate doses of intravenous blood product, 2,001 had achieved this degree of proficiency by fiscal 1981. This "home care" spared them countless hours in transit and in waiting rooms, hence the morbidity from delayed treatment. Thirty-six per cent of the surveyed population were unemployed at the outset as compared to 12.8 per cent four years later.** (The oldest regional program, New England States, had less than 7 per cent unemployment, a figure approximately equal to that of healthy persons in 1981.) The number of days lost

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* Available on request to author.

** Based on status at intake interview or annual visit during specified year divided by number of patients seen in that year.

from work or school decreased from 14.5 per year (9.4 of which were spent in the hospital) prior to funding to 4.3, with hospital treatment needed in only 1.8. The average patient, who could expect two hospitalizations per year before this program, required admission only once every three to four years, five years later.

Patient advocacy, coordinated efforts between hemophilia centers and various agencies, and the backing of the federal government resulted in third party health care coverage of 93 per cent of the patients (usually considerably more comprehensive), as compared to 74 per cent before funding.

A summary of outcomes and the average cost of services for each patient is shown in Table 1.

Discussion

The outcome parameters listed translate cogently into a quality of care which is both equitable for the individual and fiscally sound for society. They demonstrate that the hemophiliac, optimally looked after, is as capable of educating and supporting himself as any other member of society.

Because participation in the study was voluntary, it is possible that these data are biased in favor of comprehensive care. We believe this unlikely in view of the fact that all the funded centers had to compete for the federal grants and thus represented areas where the quality of services was above average even at the outset. The findings reported here are in agreement with previous reports, which have shown that an actual cost savings occurred[3-7] despite the increased use and expense of concentrate in one center. As to quality of health, the effect of state-of-the-art care on the knee—the most commonly affected joint in hemophilia—has recently been reported suggesting that with proper early management of hemarthroses, expensive surgical interventions to restore or replace joints may decrease in the future.[8] Since comprehensive centers are currently surgically rehabilitating a backlog of already severely damaged joints, we may expect overall medical costs to further decrease in the future.

Hemophilia may well serve as a model for other lifelong crippling diseases, in which the shifting of federal funds from end-stage rehabilitation programs toward comprehensive early intervention with an emphasis on home care will also be worthy of trial.

TABLE 1—Outcome Data in 11 of 22 Federally Funded Comprehensive Hemophilia Diagnostic and Treatment Centers

Outcome Data	Year before Program	Fifth Year of Program
No. patients seen at primary centers	1783	3706
No. patients seen at affiliate centers	329	1037
No. patients receiving regular comprehensive care	1333	4662
No. patients on self-infusion ("home care")	614	2001
Average days/year lost from work or school	14.5	4.3
Average hospital admission/year	1.8	0.28
Average days/year spent as inpatient	9.4	1.8
Per cent patients with third party coverage	74	93
Out-of-pocket expense/patient/year	$ 850.*	$ 342.
Overall costs of care/patient/year	$15,800.*	$5,932.
Per cent unemployed adults**	36	12.8

*These figures represent retrospective estimates from small samples, in the case of most of the centers.

**See Results section of text.

ACKNOWLEDGMENTS

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The directors of the 11 participating centers and their affiliates are as follows:

1. **California:** Shelby L. Dietrich, MD, and Edward D. Gomperts, MD, *Los Angeles, CA*; Charles F. Abildgaard, MD, *Davis, CA*; Joseph E. Addiego, Jr., MD, *Oakland, CA*.
2. **Gulf States Centers:** W. Keith Hoots, MD, *Houston, TX*.
3. **Michigan-Indiana Center:** Jeanne M. Lusher, MD, *Detroit, MI*; John A. Penner, MD, *Lansing, MI*; Ralph A. Gruppo, MD, *Cincinnati, OH*; Douglas A. Triplett, MD, *Muncie, IN*; Robert M. Weetman, MD, *Indianapolis, IN*; Leo Zelkowitz, MD, *Kalamazoo, MI*.
4. **Mountain States Regional Center** (Two major centers, one affiliate): James J. Corrigan, Jr., MD, *Tucson, AZ*; William E. Hathaway, MD, *Denver, CO*; Edward J. Hershgold, MD, *Salt Lake City, UT*.
5. **New England Comprehensive Center:** Peter H. Levine, MD, *Worcester, MA*; Louis Bove, MD, *Portland, ME*; Stanley Burns, MD, *Burlington, VT*; Cornelius Cornell, MD, *Hanover, NH*; Peter S. Smith, MD, *Providence, RI*; Frederick Rickles, MD, *Farmington, CT*.
6. **New York Centers:** Margaret W. Hilgartner, MD, Louis M. Aledort, MD, and Richard Lipton, MD, *New York City*; Mary M. Gooley, NHF, *Rochester, NY*.
7. **North Carolina Centers** (Two centers): Philip M. Blatt, MD, *Chapel Hill, NC*; Christine A. Johnson, MD, *Winston-Salem, NC*.
8. **Pennsylvania:** M. Elaine Eyster, MD, *Hershey, PA*.
9. **Tennessee:** Marion Dugdale, MD, *Memphis, TN*.

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CDC Presentation - October 11, 1985

Studies of Household contacts of Seropositive People (non sexual contacts)

Relfield	0/10	
Jason-Hemophiliacs	0/42	
Rogers(mixed)	0/86	
Rogers-Transfused Children	0/56	Total - 0/230 became seropositive
Peterman-Transfused Adult	0/36	

Rogers Study (Mixed) at Montefiore (none seropositive)

7% shared toothbrushes
9% shared razors
25% shared eating utensils
46% shared dishes
48% shared drinking glasses
37% shared bed
90% shared toilet
92% shared bath/shower
93% shared kitchen

17% kiss on lips
83% kiss on cheeks
79% hugging
21% shaking hands

Assist patient with bath	10%
Assist patient with dressing	10%
Assist patient with eating	13%

The CHAIRMAN. Mr. Levi, we are happy to have you here and look forward to hearing your testimony.

Mr. LEVI. Thank you, Mr. Chairman.

My name is Jeffrey Levi, and I am director of governmental and political affairs for tbe National Gay and Lesbian Task Force. We are a civil rights advocacy organization that has been working since the beginning of the AIDS crisis with the gay community and governments at all levels to assure an adequate response to AIDS.

I congratulate you on holding this important hearing today. In my testimony, I would like to place in perspective the impact AIDS has had on the gay community and also outline some aspects of the Federal Government's response that bear closer scrutiny by this committee in its oversight and authorizing functions.

There are now over 19,000 cases of AIDS. By the end of 1988, if current trends continue, more Americans will have been striken by AIDS than died in the Vietnam war.

We are still coping as a country with the social and psychological dislocation associated with that conflict. When you realize that three-fourths of the AIDS-related deaths are falling within 10 percent of the population, then some idea of the impact AIDS is having on the gay community can be gained.

If this objective situation were not bad enough, those with AIDS and those who are in some way associated with AIDS, usually by virtue of being in a risk group, are also victims of the epidemic of fear and discrimination.

The Public Health Service has spoken articulately on how irrational is the fear of casual contagion. Dr. Mason and the CDC have issued guidelines for employment, schoolchildren, and health care workers that are grounded in sound science and concerns for the public health.

Unfortunately, these guidelines are not being implemented as widely as we would like. My organization and many others across the country can provide countless examples of AIDS-related discrimination and even violence that have been perpetrated against those with AIDS and in all risk groups for AIDS. Individuals have been denied jobs, insurance, housing, and custody of their children.

Even in the health care professions, where providers should be better informed, discrimination abounds. For example, there are only a handful of nursing homes in the entire country that are willing to take persons with AIDS. Stories of individuals in hospitals being ignored are legion. There are metropolitan areas where it can be almost impossible to find dentists willing to treat persons with AIDS. We are seeing fear of disease and prejudice against those in high-risk groups, particularly gays, overcome a more rational response to what is admittedly a deadly epidemic.

There are some who suggest that in raising these issues, we are trying to impose our civil rights agenda on the health crisis. Nothing could be further from the truth. We understand better than anyone else the toll this disease extracts from a community. We want the death and the suffering to stop. These irrational and discriminatory responses are diverting our energies and resources from responding to the public health problem as simply that—a public health crisis of major proportions.

The response of the gay community to this crisis has been a model of voluntarism and private sector initiative. Long before any level of government began to recognize the import of this disease, gay community groups were forming AIDS service organizations around the country. To this day, they provide the foundation for and majority of education efforts and nonhospital care for persons at risk to AIDS and with AIDS. These agencies, while often originating in the gay community, are dedicated to serving all those affected by the disease.

One of the most moving examples of both discrimination and caring is the experience of Gay Men's Health Crisis and the children with AIDS at a New York hospital. Many of these children were abandoned by their parents and ignored by care givers. They were not receiving the affection and the attention that sustains all of us. To overcome this, gay volunteers from the Gay Men's Health Crisis have spent time each day holding, playing with, and providing basic human affection for these children. That to me symbolizes the depth of caring and devotion that AIDS has brought out in the gay community. It is one that any group would be proud to emulate.

Given the current state of the science of AIDS, education about how to prevent transmission of the virus is our only defense, our only hope for preventing the continued growth of this epidemic.

Despite the skepticism expressed by many about the efficacy of education as a prevention tool, we have ample evidence that such efforts work. In cities like New York and San Francisco, where substantial AIDS prevention efforts funded and implemented primarily by gay organizations have been underway for some time, the rate of sexually transmitted diseases among gay men is down dramatically. This success must be replicated across the country. This will require Federal assistance. The gay population is usually not large enough or well organized enough, nor should it be expected to underwrite the level of education that is needed in every community, particularly in the cities with low levels of infection, where education can do the most good in disease prevention.

Furthermore, the education efforts must reach beyond the gay community to all groups at risk to AIDS.

Just as we are seeing a blurring of risk groups, we are also seeing a geographic nationalization of the disease. It is no longer confined to certain major cities like New York, San Francisco, and Los Angeles. This is now a problem that every local and State health official must confront. I fear, however, that the health care system and medical establishment are not prepared to cope with AIDS in every city.

We are beginning to see a two-classs system of care for persons with AIDS: the latest in treatments, access to clinical trials, and compassionate care and services are available in high incidence communities, as compared with an inadequately prepared care system in lower incidence communities.

The Federal Government must step in to assure that the person with AIDS in Phoenix or Des Moines has the same chance for receiving the best available treatment and care as the person with AIDS in San Francisco or New York.

This committee, in using its oversight and authorizing powers, can dramatically influence how a truly national approach to this epidemic can be developed. To that end, I would urge the committee to consider the following five points.

First, the dedicated scientists and public health officials in the Public Health Service must be assured predictable and adequate funding to continue the important functions they are performing and to do so without having to rob other vital health programs.

Second, education programs must be expanded, to teach individuals in high-risk groups how to prevent transmission of the HTLV-III virus and to train health care professionals how to treat and counsel those affected by the disease. This money will be well invested. If prevention activities saved 2,600 individuals from developing AIDS, we would save $400 million in health care costs alone.

Third, clinical trials of therapeutic drugs must be expanded to assure that the entire range and combinations of antivirals and immune stimulators are fully explored and to assure greater access to these trials for persons with AIDS.

Fourth, the full spectrum of HTLV-III infection must be explored. Research into the epidemiology and natural history of AIDS-related conditions is essential to gain a better understanding of the course of HTLV-III infection.

And finally, the availability of home care and other nonhospital care must be expanded and assured in communities of all incidence levels. This is the most compassionate and most effective form of care for persons with AIDS, and it is also the least costly. We have successful models whose replication the Federal Government should be supporting throughout the country.

Mr. Chairman, I thank you for this opportunity to testify. I hope you will continue to use your position of leadership on health issues to further understanding of this awful disease, to help overcome the unfounded prejudices against those affected by AIDS, and to provide for a more complete, cost-effective response to the needs of those with AIDS and at risk to AIDS.

The **Chairman**. Thank you so much, Mr. Levi.

[The prepared statement of Mr. Levi and responses to questions submitted by Senators Hatch and Kennedy follow:]

NATIONAL
NGLTF
GAY & LESBIAN
TASK FORCE

THE IMPACT OF AIDS ON THE GAY COMMUNITY AND THE FEDERAL RESPONSE

Jeffrey Levi
Director of Governmental and Political Affairs

April 16, 1986
Senate Committee on Labor and Human Resources
Washington, D.C.

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Senate Testimony, April 16, 1986

Mr. Chairman, my name is Jeffrey Levi; I am Director of Governmental and Political Affairs for the National Gay and Lesbian Task Force. We are a civil rights advocacy organization that has been working since the beginning of the AIDS crisis with the gay community and governments at all levels to assure an adequate response to AIDS.

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There are now over 19,000 cases of AIDS. By the end of 1988, if current trends continue, more Americans will have been striken by AIDS than died in the Vietnam War. We are still coping with the social and psychological dislocation associated with that conflict. When it is realized that three-fourths of AIDS-related deaths are falling within ten percent of the population, then some idea of the impact AIDS is having on the gay community can be gained. In addition to those with AIDS are the possibly two million individuals who have HTLV-III infection or AIDS-related conditions: people faced with a life-long infection whose full implications are unknown and who live with the perpetual fear that they may go on to develop full blown AIDS.

AIDS is striking primarily young men in their; at a time when they should be planning their futures they are instead fighting for their lives. In many respects, those around people with AIDS—often called the worried well—are faced with equally difficult issues: each time we bury one of our brothers we must confront our own mortality.

If this objective situation were not bad enough, those with AIDS and those who are in some way associated with AIDS--usually by virtue of being in a risk group--are also victims of the epidemic of fear and discrimination. The Public Health Service has spoken articulately on how irrational is the fear of casual contagion. Dr. Mason and the CDC have issued guidelines for employment, school children, and health care workers that are grounded in sound science and concerns for the public health. Unfortunately, these guidelines are not being implemented as widely as we would like. My organization and many others across the country can provide countless examples of AIDS-related discrimination and even violence that has been perpetrated against those with AIDS and in all risk groups for AIDS. Individuals have been denied jobs, insurance, housing, and custody of their children. Even in the health care professions, where providers should be better informed, discrimination abounds. For example, there are only a handful of nursing homes in the entire country that are willing to take persons with AIDS; stories of individuals in hospitals being ignored are legion; there are metropolitan areas where it can be almost impossible to find dentists willing to treat persons with AIDS. We are seeing fear of disease and prejudice against those in high-risk groups, particularly gays, overcome a more rational response to what is admittedly a deadly epidemic.

There are some who suggest that in raising these issues we are trying to impose our civil rights agenda on a health crisis. Nothing could be further from the truth. We understand better than anyone the toll this disease extracts from a community. We want the death and the suffering to stop. These irrational and discriminatory responses are diverting our energies and resources from responding to the public health problem as simply that--a public health crisis of major proportions.

The response of the gay community to this crisis has been a model of voluntarism and private sector initiative. Long before any level of government began to recognize the import of this disease, gay community groups were forming AIDS service organizations around the country. To this day, they provide the foundation for and majority of education efforts and non-hospital care for persons at risk to AIDS and with AIDS. They are supported primarily by private donations and dedicated volunteers. Some of these service providers are well on their way to becoming the largest private social service agencies in their communities. And these agencies, while often originating in the gay community, are dedicated to serving all those affected by the disease. One of the most moving examples of discrimination and caring is the experience of Gay Men's Health Crisis and the children with AIDS at a New York hospital. Many of these children were abandoned by their parents and ignored by care givers. They were not receiving the affection and attention that sustains all of us. To overcome this, gay men from GMHC have volunteered to spend time each day holding, playing with and providing basic human affection for these children. That, to me, symbolizes the depth of caring and devotion that AIDS has brought out in the gay community. It is one that any group would be proud to emulate.

Given the current state of the science of AIDS, education about how to prevent transmission of the virus is our only defense, our only hope for preventing the continued growth of this epidemic. There are three levels of education that are critical: the first is to the general public to help overcome their needless fears of casual contagion; the second is to educate health and service providers to assure that those affected by this disease receive quality and appropriate care; and the third is to reach those at risk—to encourage them to change their behavior to reduce the likelihood of transmitting the virus. Far greater efforts are required in all three areas if we are to contain this epidemic.

Despite the skepticism expressed by many about the efficacy of education as a prevention tool, we have ample evidence that such efforts work. In cities like New York and San Francisco, where substantial AIDS prevention efforts funded and implemented primarily by gay organizations have been under way for some time, the rate of sexually-transmitted diseases among gay men is down dramatically. This means that behaviors have changed so that fewer sexually-transmitted diseases, including AIDS, are being spread. This success must be replicated across the country. This will require federal assistance: the gay population is usually not large enough or well-organized enough, nor should it be expected, to underwrite the level of education that is needed in every community, particularly in the cities with low levels of infection where education can do the most good in disease prevention. Furthermore, the education efforts must reach beyond the gay community to all groups at risk to AIDS.

While STD rates among gay men have declined, those rates continue to rise among heterosexuals at a time when there is greater concern about heterosexual transmission of AIDS. This makes difficult to understand why the CDC has chosen to divert resources from STD prevention and education programs for AIDS. There is no doubt that more resources are needed in AIDS. Unfortunately, in many agencies of the PHS, these are gained at the expense of other vital health prevention programs. It is all the more ironic in this specific instance since these traditional STD prevention programs may be our best vehicle for teaching sexual practices to heterosexuals that might also indirectly teach them how to prevent transmission of HTLV-III. (This may be our primary means since most heterosexuals still do not perceive themselves as at risk to AIDS. The message must be transmitted indirectly through prevention of other diseases that are of concern.)

Just as we are seeing a blurring of risk groups, we are also seeing a geographic nationalization of the disease. It is no longer confined to certain major cities like New York, San Francisco, and Los Angeles. This is now a problem that every local and state health official must confront. I fear, however, that the health care system and medical establishment are not prepared to cope with AIDS at all levels. We are beginning to see a two-class system of care for persons with AIDS: the latest in treatments, access to clinical trials, and compassionate care and services are available in high-incidence communities as compared with an inadequately prepared care system in lower-incidence communities. The federal government must step in to assure that the person with AIDS in Phoenix or Des Moines has the same chance for receiving the best available treatment and care as the person with AIDS in San Francisco or New York. This requires, among other things, transferring medical knowledge rapidly and expanding access to clinical trials. Federal assistance will also be needed to help localities replicate the San Francisco model of quality care for persons with AIDS that minimizes hospitalization and saves dramatically on health care costs.

This committee, in using its oversight and authorizing powers, can dramatically influence how a truly national approach to this epidemic can be developed. To that end, I would urge the committee to consider the following five points:

o First, the dedicated scientists and public health officials in the PHS must be assured predictable and adequate funding to continue the important functions they are performing and to do so without having to rob other vital health programs.

o Second, education programs must be expanded: to teach individuals in high-risk groups how to prevent transmission of the HTLV-III virus and to train health care professionals how to treat and counsel those affected by the disease. The focus of these efforts must be broader than in the past, to include in particular I.V. drug users, adolescents, and those in low-incidence communities where awareness about AIDS may still be low. This money will be well invested; if prevention activities saved 2,600 individuals from developing AIDS, we would save $400 million in health care costs alone.

o Third, clinical trials of therapeutic drugs must be expanded to assure that the entire range and combinations of anti-virals and immune stimulators are fully explored and to assure greater access to these trials for persons with AIDS.

o Fourth, the full spectrum of HTLV-III infection must be explored. Research into the epidemiology and natural history of AIDS-related conditions (ARC) is essential to gain a better understanding of the course of HTLV-III infection and what can be done to care for and possibly halt the progress of the disease. We do not fully understand the scope of the ARC problem. While not a fatal condition, ARC is chronic and its impact on the lives of those affected and the associated burden on the health care system are issues that must be addressed.

o Finally, the availability of home care and other non-hospital care must be expanded and assured in communities of all incidence levels. This is the most compassionate and most effective form of care for persons with AIDS—and it is also the least costly. We have successful models whose replication the federal government should be supporting throughout the country. Whatever the cost involved in establishing such demonstration programs, the savings in the federal share of Medicaid alone will be far greater.

Mr. Chairman, I thank you for this opportunity to testify. I hope you will continue to use your position of leadership on health issues to further understanding of this awful disease, to help overcome the unfounded prejudice against those affected by AIDS, and to provide for a more complete, cost-effective response to the needs of those with AIDS and at risk to AIDS.

AIDS, Insurance, and Antibody Testing

National Gay and Lesbian Task Force
March 1986

I. The Problem

AIDS is a critical public health problem for the nation and the state of Maryland. There have been over 260 cases reported in Maryland, with at least as many more anticipated in the coming year. AIDS is a personal tragedy for those whose lives are touched by it. It is also a potential financial disaster for people with AIDS, their loved ones, and local governments in the areas in which they live.

Recent studies have estimated the cost of hospitalization alone at nearly $150,000 for every case of AIDS. This does not include other health-care costs such as outpatient doctors' bills, tests, and drugs, and home health care. Lost income due to disability has been estimated at nearly $20,000 per case. Loss of lifetime earnings due to premature death has been estimated at $460,000 per case. These figures do not include cases of AIDS-related complex (ARC) that can be equally disabling and also very costly.

WHO IS GOING TO PAY FOR THIS?

People with AIDS and their loved ones will be unable, except in rare cases, to pay these costs from their own resources. They will have three alternatives:

1. To insure themselves against these losses.
2. To depend on public assistance, such as Medicaid, public hospitals, and public disability benefits.
3. To forego medical care, sell their homes and possessions, spend the last months of their lives homeless and impoverished, and leave their dependents in debt and without support.

The third alternative is morally unacceptable. The second is inadequate and would burden the public budget. Now, some private insurance companies are threatening to eliminate the first option.

WHAT IS THE RESPONSE OF THE INSURANCE INDUSTRY?

Many insurance companies have recognized and accepted their obligation to pay those costs of AIDS that are traditionally covered by private health, disability, and life insurance. Other companies, however, are seeking to evade this responsibility and shift it to the public treasury.

A number of major insurers are currently attempting to screen out the costs of AIDS; these include Lincoln National Corporation, Midland Mutual Life, Munich American Reassurance Company, Northwestern Mutual Life, and Transamerica Occidental Life. Reports by industry sources indicate that other companies are doing the same.

AIDS, Insurance, and Antibody Testing

There are two methods of screening:
1. To exclude from coverage any expenses or lossses resulting from AIDS.

2. To deny coverage to persons considered at high risk of AIDS. There are two principal means of screening applicants:

(a) "Red-lining" is the identification of demographic factors associated with high-risk groups, particularly gay men. Some industry officials have said that any gay man or hemophiliac is an unacceptable insurance risk. Since there is no efficient way to identify gay men directly, insurers propose to exclude, for instance, unmarried men aged 20-50, living in certain areas (as large as a metropolitan area with a high incidence of AIDS, or as small as a zip code or even a block where gay men are thought to live), or working in certain occupations (one actuary has suggested that single men working in "creative" fields be closely scrutinized).

(b) "Red-lining plus" is the use of medical tests only for applicants who are first red-lined by one or more of the factors in (a) above. Insurers readily admit that it would be too expensive to administer such tests to every applicant; moreover, tests now available are considered fairly reliable when used in "high-risk" populations but unreliable in "low-risk" populations.

The tests most commonly proposed for use are those that detect antibodies to HTLV-III in the blood. HTLV-III (human T-lymphotropic virus, type 3) has been identified as the probable cause of AIDS and ARC. Antibodies indicate infection, and 5-10% of those infected will eventually develop AIDS. Someone testing negative, in contrast, is probably not infected (although antibodies may not develop for six months after infection) and thus will not develop AIDS.

Screening for risk of AIDS by private insurance companies, if allowed, would be both unfair and very costly to the public.

UNFAIR because:
1. People will be denied coverage who will never develop AIDS. Simple red-lining--e.g., unmarried men in a zip code--will obviously exclude large numbers of people at no risk of AIDS. But even the most sophisticated medical testing will identify only people with a 10% risk of AIDS. The other 90% will probably not develop AIDS. Yet, all those screened out will be uninsured against major medical bills, disability and death from other causes.

2. Some people with AIDS will be covered while others will have been screened out.

(a) People not red-lined will not be tested, though many of them will be at high risk. Gay men, for instance, live in every geographic area and work in every occupation, as do other people at risk: intravenous drug users and their sexual partners, bisexual men and their female sexual partners, hemophiliacs and their sexual partners, etc. The Kinsey study estimated that 30% of all men engage in homosexual activity at least incidentally; all such men are at risk of AIDS, though most would not consider themselves gay. Indeed, the demography of this epidemic is changing and assumptions that it is a "gay disease" are already outmoded. As heterosexual transmission increases, red-lining will become a less and less efficient means of identifying risk.

(b) Those who test negative may be infected but have not yet developed antibodies, or they may contract the virus after testing.

People denied coverage may be forced onto public assistance. Even then, they may lose their homes and possessions when they need them most.

3. Screening will force people to take the antibody test. Most people applying for insurance would not ordinarily choose to be tested, as there is no medical benefit to the person who knows their antibody status, while they may reasonably fear negative consequences. For instance, calls for quarantines have been given credence by the media, and by public officials in some parts of the country. Discrimination in employment, housing, and even health care is occurring everywhere against people with AIDS and people thought to be at risk. Many people learning they are positive for antibodies experience severe psychosocial trauma; some have committed suicide.

4. It will infringe on privacy. While insurers are looking for the most part at demographic screening, some have discussed ways of identifying sexual orientation directly, through inquiries or investigation into an applicant's sexual orientation or practices. Such intrusive inquiries into people's private lives should not be encouraged.

VERY COSTLY because:

The bills have to be paid by someone. Only the very wealthy will be able to pay the tremendous costs of AIDS. Everyone else will turn to Medicaid, public hospitals and clinics, and public disability benefits. If they die without life insurance, their dependents could be forced onto public assistance, and there will be generalized economic loss from unpaid debts.

The New York Hospital Association stated recently that "changes ... in the [insurance] benefit structure surrounding AIDS ... could be disastrous for both patients and providers." Public resources are already strained by the enormous costs of treating and caring for AIDS; with the number of cases expected to double in 1986 and again in 1987, these costs will rapidly become unmanageable.

II. Possible Solutions

To meet these concerns and guarantee continued access to insurance by entire classes of individuals, legislation or regulation is needed to prohibit the following practices in health, disability, and life insurance:

1. Exclusion of AIDS from coverage.
2. Requirement of the HTLV-III antibody test, or other tests to screen for any probable causitive agent of AIDS, ARC, or the HTLV-III infection. That is, the insurer cannot require an applicant to take the test, or to reveal the

results of the test if he has taken it.

3. Red-lining. Insurers should not consider in the determination of rates, benefits, or any other aspect of marketing or coverage any factor used to predict whether any individual may in the future develop AIDS or ARC, including the age, marital status, residential address, sex, or sexual orientation of the individual.

Of course, insurance companies should not be required to pay the costs of AIDS or ARC if the insured had already been diagnosed before the policy was issued.

It should be noted that these approaches are not unprecedented. Social decisions have been made in a number of jurisdictions to guarantee insurance coverage to those carrying sickle cell trait, Tay Sachs trait, or were exposed to DES. While not directly comparable medically, the principle remains the same: with a rate differential for these groups, insurance rates would make coverage unaffordable.

These proposals are not made without regard for the financial impact AIDS is having on insurance companies. To protect the fiscal viability of the insurance industry, we would suggest several measures to limit the adverse impact of AIDS claims.

(1) Create a shared-risk (or reinsurance) pool among health insurance companies in the state. It is useful to note that the push for restrictive measures around AIDS is coming generally from smaller companies with fewer clients among whom the risk of AIDS can be spread. By drawing funds from a statewide pool for AIDS claims above a prescribed amount, the risk will be more evenly shared and the fiscal impact on companies less significant.

(2) Create some built-in protections in life insurance policies to prevent someone recently testing positive from buying unusually large amounts of coverage. Included would be a contestability clause--a period of two or three years during which, if a person died of AIDS, benefits need not be paid.

What these alternatives show is that the interests of all--the insurance companies, those individuals in high-risk groups, and the public sector--can be met with some creativity and compromise on all sides. We do not need to seize on the first available tool, the HTLV-III antibody test, simply because it is there without due consideration to the broader implications of the test.

Responses to written questions by Jeffrey Levi

Question from Senator Hatch:

What additional assistance has proved useful for families and friends of AIDS patients?

The assistance needed by families and friends of persons with AIDS—as well as ARC or HTLV-III infection—are those traditionally associated with a serious or terminal illness. However, the social stigma is greater and the adjustment in the physical relationship with the person with AIDS is a serious one for the spouse.

Support groups, counseling, and assistance with home care are critical elements of the assistance needed. Special instruction regarding what risk reduction precautions are necessary and not needed are important. Support in dealing with the hostility and fears toward a friend or family member of a person with AIDS will be needed. Even legal assistance from human rights agencies may be necessary to fight discrimination in the workplace or schools.

Questions from Senator Kennedy:

What problems have been encountered with regard to access to health and life insurance as a result of AIDS? What kind of discrimination is occurring? What about use of the HTLV-III antibody test as part of underwriting?

See attached position paper prepared for the Maryland AIDS Task Force.

What is your community's position on the use of the HTLV-III antibody test as part of a prevention strategy? Is there sufficient funding for testing and associated counseling?

The following is a consensus statement on HTLV-III testing and related issues that has been endorsed by over a dozen national and local gay and AIDS service organizations around the country. Unfortunately, there is insufficient funding for quality testing programs. The value of the test is only as great as the counseling associated with it. That makes a major testing program an expensive proposition. Testing without counseling can, in fact, be counterproductive. If the PHS's recommendations for broader testing are going to be adopted by the states, then more funds will be needed to support that program.

Consensus Statement on HTLV-III Antibody Testing and Related Issues

We who work most closely with AIDS, and who have been and still are at the forefront of the fight against AIDS, firmly believe that every valid tool available to fight this disease should be employed. However, the existence of a test does not in and of itself justify its broad-scale use, unless valid medical or public health justifications can be made. This statement delineates what we believe to be the legitimate and dangerous uses of HTLV-III testing.

I. Antibody Testing

The HTLV-III antibody test measures exposure to and probable infection with the virus associated with AIDS. It does not diagnose AIDS nor is its predictive value fully known. For the purpose of prevention, it is prudent to assume the individual is infected, although this test is not proof of ongoing infection. The presence of antibodies is correlated with HTLV-III infection. It is known that some of those infected will go on to develop AIDS or AIDS-related conditions and that some will remain asymptomatic at least for five to seven years. Current studies show that the majority of those testing HTLV-III antibody positive will remain asymptomatic.

Unfortunately, there is no medical intervention for those who test positive. At this time, the principle advice that can be given someone who tests positive is to follow safer sex and other risk reduction guidelines (i.e. not exchanging blood or semen with sex or IV drug using partners). However, these are recommendations that should be followed by any member of a high-risk group, whether they have tested positive or negative. (Individuals who are positive should avoid passing on the virus to others and avoid their own reinfection; individuals who are negative should avoid becoming infected. It should be noted that two partners in high-risk groups who have tested negative should also follow these guidelines because of the delay period between infection and development of antibodies.)

It has been suggested that knowledge of antibody status will result in greater incentive to follow risk reduction guidelines. We have no data to prove this suggested consequence of testing. We do, however, have data that show that basic education does work to reduce transmission, as judged by dramatically lower STD rates in cities like New York and San Francisco, using programs that do not use the antibody test.

We believe the decision to take this test should be an individual decision given the tremendous psychological, legal, social, and economic impact a positive test result can have on a person's life. Persons must be given the latitude to decide for themselves whether testing will help them reduce their risk. When the test is performed, it must be with the full informed consent of the individual. The informed consent process must be specific for this test; it cannot be part of a standard or general waiver associated with a battery of other tests. The consent process should outline what positive and negative test results do and do not mean, the potential psychological impact of learning one is antibody positive, and the possibilities for difficulties in insurability (insurance companies across the country are seeking to use the test as a basis for denying insurance to those who test positive) and employability (some employers are already attempting to screen their employees for antibodies even though there is no business justification for such testing) if a positive test result is known. They should also be told that in some jurisdictions test results are reported to public health authorities (and this is a possibility in others), and the extent to which the agency offering the test will provide counseling. (Supportive psychological counseling by informed and sensitive professionals is essential to any testing program.)

Given these dangers just outlined above, as well as the potential for quarantine of individuals who test positive (as has been suggested in some states), testing should be done on an anonymous basis to protect the confidentiality of those being tested. Anonymity is the only true assurance of confidentiality. Even where initially strong protections exist, there are at least four means by which they can be violated: through legislation overriding the initial protections, when a subject must voluntarily signs away the confidentiality protections as part of an employment or insurance application (as can be done under Colorado's reporting system, for example), through a court subpeona, and through informal disclosure by those who have access to the test results. Without guaranteed protections, individuals who need the test to alter their behavior are likely to be afraid to take it. The U.S. Public Health Service recently recommended mass testing on a voluntary basis of individuals in high-risk groups. We believe that this undermines the principle that taking the test must be a very individual decision. In addition, such a program will divert scarce resources from education and counseling programs that have been proven successful in reducing transmission of HTLV-III to a program of unproven value. It also fails to recognize that the nature of the decision may vary according to what purpose the test may serve. For example, high-risk women thinking of having children should be tested, but a blanket statement for gay men, on the other hand, is inappropriate.

The PHS guidelines also fail to adequately address the issues of informed consent and confidentiality. Furthermore, they fail to take into account the widespread discrimination accompanying use of the test. For the government to suggest mass testing without taking measures to prevent the discrimination that may result from such a program is counterproductive.

II. Reporting of Antibody Test Results and Contact Tracing

The first step in any use of this test to change behavior involves convincing the individual to be tested. If individuals fear that information relating to their status might fall into the wrong hands, they will not consent to the test. We oppose reporting test results with identifiers to state authorities. Within STD clinics, or within state health department bureaucracies, assurances that these results will be kept confidential in the same manner as other STD information are simply not adequate. AIDS is not like other STDs. The stigma associated with AIDS is far greater than with other STDs and the desire of other government and nongovernment agencies to obtain AIDS-related information is also greater. The existence of sodomy laws in nearly half the states, and the failure of all but one state to provide protection against discrimination based on sexual orientation add to the fears associated with reporting. In the context of political hysteria that is often generated around AIDS, how certain can we be that health officials will resist public pressure to turn over names of those who are antibody positive to school officials, police departments, and others?

We seriously question the value of contact tracing, even on a voluntary basis. While contact tracing may be a traditional technique for managing the spread of

STD's, AIDS is not a typical STD. There is no medical intervention for AIDS as there is for syphillis. We are not opposed, however, to voluntary contact notification by the person who has tested positive. Indeed, recommendations for such notification should be part of the counseling process for those who test positive. Our concern is with the government playing a direct role.

It must be noted that the potential of contact tracing could have the effect of encouraging anonymous sexual contacts. Someone fearful that in the months ahead his or her name might be turned over to health officials as the sexual contact of an antibody positive individual, might refuse to give an accurate name to an individual—thereby eliminating the possibility for informal contacting by an infected person of his/her contacts. This is quite plausible given the number of people using false identifiers in current antibody testing programs.

We would argue, then, that the most effective use of the test is one that is voluntary, and guarantees anonymity and appropriate counseling. Anything more intrusive is likely to diminish the confidence of the very people a risk reduction program is seeking to reach.

The CHAIRMAN. Let us turn to you, Mrs. Kushnick, and finish with your testimony on this panel.

Mrs. KUSHNICK. Thank you, Senator Hatch.

Senator Hatch, I would like to personally thank you for convening these hearings and for inviting me here to speak.

Two years ago this week, I appeared before the Labor, Health and Human Services Subcommittee on NIH Funding to ask for additional Federal funding for AIDS research, and to urgently address the issue of blood transfusion AIDS. My 3-year-old son, Sam, had been dead for 6 months of AIDS contracted from blood transfusions.

Over the course of the past 2 years, I have met with the Assistant Secretary for Public Health, the Director of the Centers for Disease Control, and the president of the American Red Cross, among others. I have spoken personally to a number of Senators and Congressmen. My family participated in the CDC study of AIDS transmission among family members. And I was a member of the symposium that helped write the guidelines for children with AIDS in the schools and foster care settings and am currently a member of the board of directors of the American Foundation for AIDS Research, whose national chairperson is Elizabeth Taylor.

Sam has been dead for 2½ years now—almost longer than he lived. What was clear to my family in October 1983, as we watched Sam die a very painful death, was that AIDS was an illness, a devastating illness, and because it had been mislabelled a syndrome confined to the homosexual community, this Nation was subjected to years of apathy on the part of the Government in the struggle ~~against this~~ deadly killer.

Where we have failed and, I believe, continue to fail as a society in general is in the social and political issues. The fear is still there, and the apathy in most instances has turned to hysteria.

As my son lay dying of a disease no one knew how to treat in a child, his twin sister was asked to leave the nursery school she was attending for fear she might contaminate the other children—even after she was subjected to a battery of immunological tests requested by the school and pronounced healthy. To quote the head of Los Angeles County Health, "The community went berserk."

We were able to place her in another nursery school, which she attended for 2 years. During 1984 and 1985, we made a number of applications to private grade schools; all were rejected. Coincidence? Perhaps.

This past September, Sara entered public school. As required by law, she had received a full physical and been immunized. However, shortly after school began, I was called by the principal and asked for an additional letter from her doctor stating that she was healthy, because the school had recieved a number of calls from concerned parents—this, even though her brother has been dead for over 2 years.

The insurance company that provided our medical insurance tried to claim a preexisting condition so that they would not have to pay the $94,000 in medical costs for Sam's 19-day hospital stay until his death. They lost. They paid. Then they canceled our policy.

Let me tell you about my friend who I am going to call Mrs. Smith. She is black. She is a single parent. Her 3-year-old son also has AIDS contracted from a blood transfusion. She also has a 6-year-old daughter. She works as a teacher's aide. She tells no one that her son has AIDS because she does not feel she can fight the isolation and the discrimination of herself and her daughter were the facts known.

So Mrs. Smith goes underground, as do most of the families who have a child with AIDS. The most horrendous part of AIDS is fear and rejection. It is hard enough for an adult to cope with, and impossible to explain to a child.

There are AIDS cases in every State, yet Amy Sloan in Lafayette, IN, is denied a drug treatment program because there are only 60 AIDS cases in the State of Indiana. Isn't Mrs. Sloan entitled to the same chance to live as patients in Washington, DC, California, New York, and Florida?

Early on in this epidemic, the money for research and clinical funding was centered at the NIH in Washington, and the clinical research centers around the country had been closed because of budget cutbacks. This is still the case. The only growth has been in the patient population.

While the doctors at NIH all compete with each other for air time to announce their latest findings—as with compound S—people around the country are being denied drug treatment programs. And if, as these NCI or NIH doctors say, more testing is necessary on these drugs, why are they talking about them on the CBS evening news? These are doctors, by the way, who are paid with Federal funds. They hold out hope, and then they take it away. This really gives "cruel and inhuman punishment" a new definition.

Senators, we are a homophobic society, meaning that most people are uncomfortable dealing with homosexuals. There are those who would prey on that fear, and the way for them to do that is to argue that the virus can be spread by casual contact. Yet studies prove, and overwhelmingly so, that there is no medical evidence to suggest that AIDS is transmitted by casual contact, and that with all the cases of AIDS, both pediatric and adult, there has been no transmission of a virus in a family setting.

Yet Ryan White and dozens of other children around the country have to fight for their right to go to school; others are denied jobs, housing, medical insurance, and are subject to indiscriminate violence. As one who has dealt first-hand with the medical community in a crisis situation, I can tell you that clearcut medical information is hard to come by—actually, it is almost impossible.

We have grown, a specialized medical community in this country in the last 40 years, more concerned with personal liability than the Hippocratic oath. The medical and scientific communities rarely agree on anything. Government agencies such as Public Health and the Surgeon General, have not utilized educational media such as television and radio to properly educate the public.

Until we find a cure or a vaccine, the only way to stop the spread of AIDS is through education. We need effective educational programs designed by those qualified to disseminate the information in every State in this Nation, and we have to start by educating the practicing physician. As any rational human being knows, tatooing and quarantine are not the answers to preventing the spread of AIDS; education is—and not behind the disease, but in front of it; not after someone with AIDS is found in the school or workplace, but before. We need effective adolescent sexual education programs in our schools, working with the PTA's, and we need them now.

One of the best educational tools this past year was an episode of the 20th Century Fox ABC television series entitled, "Mr. Belvedere". "Wesley's Friend" was an eight-year-old hemophiliac AIDS patient. I have brought a copy of the show for you to view, either individually or collectively.

I would like to talk for a moment about the HTLV-III antibody test. This test is not a test for the disease. It is simply a test for specific antibodies to the HTLV-III virus, and it was developed as a tool to try to make the blood supply safer. For Government agencies to make overly optimistic statements regarding the safety of the Nation's blood supply because of pressure from special-interest groups is an attempt to eliminate public pressure to develop a better and more specific test. It has been proven that the antibodies that this test measures may not appear in the blood for 11 months after infection with the virus, and there is no way to know how many of the people who are positive will go on to get AIDS. Yet the Government is using this test on military personnel. How can we expect the American public and the private sector to act responsibly when the Government will not?

Please, let us stop this insanity. The money spent to administer and process this test would be better spent in finding a better test.

If AIDS is truly considered the number one health priority, why isn't there a National AIDS Institute as part of NIH? At the moment, research is scattered through NIH and NCI. Grant applications still take up to 18 months to process through NIH. We do not have that kind of time. The American Foundation for AIDS Research has been in existence for 6 months. Our first set of grant proposals will be made in the next few weeks.

There are some wonderful research projects going on around the country, but they are not funded. Some of those applying for grants, by the way, for our foundation, are NIH doctors who are afraid that their funding is going to be cut off.

During World War II, the Federal Government was able to bring together the best scientific minds in the world to create the atomic bomb. Some of the best scientific minds in the world are now suing each other over patent rights in their quest for the Nobel Prize and the others are up to their necks in grant applications. This alone should tell us that the system for medical research and care in this country is sorely lacking. The AIDS epidemic has shown us just how poorly we are doing.

Seven lives were lost when the *Challenger* exploded, and the country mobilized. By the next Presidential election more people—men, women, and children—will die of AIDS than died in the Vietnam War, and the social and psychological damage to surviving family members will be devastating.

I beg you to urge the administration to form a Presidential commission on AIDS so that the American public can be educated through the proper channels, so that the National AIDS Network and the American Foundation for AIDS Research—the two groups which represent the private sector—can work effectively to educate the public and prevent the spread of this syndrome in a calm and rational manner while our scientists search for a vaccine and cure.

This virus has really become a test of our metal as human beings. Please, do not let us fail.

Thank you.

The CHAIRMAN. Thank you, Mrs. Kushnick.

[The prepared statement of Mrs. Kushnick and responses to questions submitted by Senators Hatch and Kennedy follow:]

UNITED STATES SENATE
COMMITTEE ON LABOR AND HUMAN RESOURCES

HEARINGS, WEDNESDAY, APRIL 16, 1986

WITNESS: MRS. HELEN G. KUSHNICK

SUBJECT: EFFECTS OF OUR NATIONAL EFFORT IN AIDS RESEARCH, PREVENTION AND TREATMENT. DISCUSSION ON HEALTH POLICY ISSUES INVOLVING THE PUBLIC AND PRIVATE SECTORS DEALING WITH AIDS.

Two years ago this week, I appeared before the Labor, Health and Human Services subcommittee on NIH Funding to ask for additional federal funding for AIDS research, and to urgently address the issue of blood transfusion AIDS. My 3-year-old son, Sam, had been dead for six months of AIDS contracted from blood transfusions he had received as a neo-nate at Cedars-Sinai Hospital in Los Angeles.

Sam has been dead for 2 1/2 years now, almost longer than he lived. In 1983, my family's decision to go public with our story seemed courageous because of the fear and suspicion surrounding AIDS. To us it was simply a matter of not having a choice. It was clear to us then that AIDS had been mislabeled a syndrome confined to the homosexual community and that mislabeling caused years of apathy on the part of the public and the government in the struggle against this deadly killer.

Over the course of the past two years, I have met with the Assistant Secretary for Public Health, the Director of the Centers for Disease Control, and the President of the American Red Cross, among others. I have spoken personally to a number of senators and congressmen. My family participated in the CDC study of AIDS transmission among family members. I was a member of the symposium that wrote the guidelines for children with AIDS in the schools and foster-care settings published by the CDC in August of 1985 and am currently a member of the board of the American Foundation for AIDS Research.

I would like to sit here today and tell you that everything is wonderful in terms of education, care and research on AIDS, but it isn't. The fear is still there, the suspicion lingers and the apathy, in most instances, has turned to hysteria. The only growth has been in the number of cases and deaths.

As my son lay dying, his twin sister was asked to leave the nursery school she was attending for fear she might contaminate the other children. We were able to place her in our own temple nursery school which she attended for two years. We made a number of applications to private grade schools during 1984 and 1985. All were rejected. This past September, Sara entered public school. As required by law, she had received a full physical and had been immunized. However, shortly after school began, I was called by the principal and asked for an additional letter from her doctor stating that she was healthy because the school had received a number of calls from concerned parents -- this even though my daughter is exceptionally healthy and more than two years have passed since her brother's death.

The insurance company that provided our medical insurance tried to claim a "pre-existing condition" so that they wouldn't have to pay the $94,000 in medical costs for Sam's 19-day hospital stay until his death. They lost. They paid. Then they cancelled our policy. Today, thousands of Americans are being denied medical coverage because insurance companies have calculated the cost of caring for an AIDS patient at upwards of $150,000 per patient.

There are AIDS cases in every state. Yet Amy Sloan, in Lafayette, Indiana, is denied a drug treatment program because there are "only" 60 AIDS cases in the state of Indiana. Isn't Mrs. Sloan entitled to the same chance to live as patients in California, New York and Florida? By the way, I am told that there is no funding for AIDS, either on a state or federal level, in Indiana.

Where do AIDS patients live when they can no longer care for themselves? Most, especially the children, are living in hospitals because there is no place for them to go. And when someone like Dr. Elizabeth Kubler-Ross attempts to privately fund a home for these children, the neighbors said "no, we don't want these kids in our neighborhood".

Let me tell you about my friend whom I will call "Mrs. Smith". She is black and a single parent. Her three-year old son also contracted AIDS through a blood transfusion. She has a daughter six years of age. She works as a teachers aid. She tells no one that her son has AIDS because she doesn't feel she can fight the discrimination and isolation of herself and her daughter were the facts known. As everyone here knows, the most horrendous part of this disease is fear and rejection. It is hard enough for an adult to cope with, and impossible to explain to a child. So "Mrs. Smith" goes underground as do most of the families who have a child with AIDS.

Studies prove that there is no medical evidence to suggest that AIDS is transmitted by casual contact and that, with all the cases of AIDS, both pediatric and adult, there has been no transmission of the virus in a family setting. Yet Ryan White, and dozens of other children around the country, can't attend school. How far do we, as human beings, go to protect the children? Do we take it to the extent of mindless cruelty?

Clear cut medical information _is_ hard to come by, actually almost impossible. The public first has to understand that the medical and scientific communities rarely agree on anything. So who do we go to for our information? Most often to the media. Government agencies have not utilized educational media, such as television and radio. As a result, the news media has reported its own versions of events which, in some instances, have been sensational, inaccurate and have provided little public health information.

Until we find a vaccine or cure, the only way to stop the spread of AIDS is through education. We need effective educational programs, designed by those qualified to disseminate the information, in every state in this nation regardless of how few AIDS cases are statistically counted. Because the statistics are wrong, and those people with ARC aren't being counted. As any rational human being knows, tatooing and quarantine are not the answers to preventing the spread of AIDS. _Education is_. And not _after_ someone with AIDS is found in the school or the workplace, but _before_.

On January 31, 1986, the ABC Television Network aired an episode of the 20th Century Fox television series "MR. BELVEDERE" entitled "Wesley's Friend" written and produced by Frank Dungan, Jeff Stein and Tony Sheehan. Wesley's friend was an 8 year old hemophiliac AIDS patient. To quote Deborah Rizzi of United Hospitals Medical Center in Newark, New Jersey, this episode "represents responsible journalism at its best." (A full copy of her letter is attached.) I have brought a copy of the show with me today and urge you all to see it. 20th Century Fox is making this show available to all PTAs, schools and hospitals which request it.

Let's talk for a moment about the HTLV-III antibody test. This test is not a test for the disease. It is simply a test for specific antibodies to the HTLV-III virus. For government agencies to make overly optimistic statements regarding the safety of the nation's blood supply, because of pressure from special interest groups, will eliminate public pressure to develop a better and more specific test. It has been proven that the antibodies that this test measures may not appear in the blood for 11 months after infection with the virus. And there is no way to know how many of the people who are positive will go on to get AIDS. Yet the government is using this test on military personnel. How can we expect the American public and the private sector to act responsibly when the government will not. Please let us stop this insanity. The money spent to administer and process the test on military personnel would be more wisely used in finding a better test.

If AIDS is truly considered the number one health priority, why isn't there a National AIDS Institute as part of the NIH. At the moment, research is scattered through NIH and the National Cancer Institute. The American Foundation for AIDS Research has received a number of grant applications from NIH doctors fearful that their funding will be cut off.

During World War II, the federal government was able to bring together the best scientific minds in the world to develop the atomic bomb. The best scientific minds in the world are now suing each other over patent rights. This alone should tell us that the system for medical research and care in this country is sorely lacking. The AIDS epidemic has showed us just how poorly we're doing.

Seven lives were lost when the Challenger exploded and the country mobilized. By the next presidential election, more people, men, women and children, will die of AIDS than died in the Vietnam War and the social and psychological damage to the surviving family members will be devastating. I beg you to urge the Administration to form a Presidential Commission on AIDS so that the American public can be educated through proper channels, so that the National AIDS Network and the American Foundation for AIDS Research, the two groups which represent the private sector, can work effectively to educate the public and prevent the spread of this syndrome in a calm and rational manner.

UNITED
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MEDICAL
CENTER 15 SOUTH 9TH STREET, NEWARK, NEW JERSEY 07107 • TELEPHONE: (201) 268-8000

- Presbyterian Hospital
- Children's Hospital of New Jersey
- Newark Eye and Ear Infirmary
- Eye Institute of New Jersey
- United Hospitals Orthopedic Center

February 4, 1986.

Mr. Frank Dungan
c/o Mr. Belvedere
Lazy B/F.O.B. Productions
4151 Prospect Blvd.
Production Bldg. #1
Hollywood, California 90027

Dear Mr. Dungan:

On behalf of the Children's Hospital AIDS Program (CHAP) at Children's Hospital of New Jersey, I would like to commend you for your outstanding episode of "Mr. Belvedere" which aired on January 31, 1986.

As one of the largest pediatric AIDS centers in the United States, directed by one of the country's foremost experts on pediatric AIDS (Dr. James Oleske), we are painfully aware of the persecution of children who have AIDS. We are also aware of the high level of fear and anxiety created by misunderstanding and misinformation about the disease.

Your episode of "Mr. Belvedere" put forth the facts simply and honestly. The parents reacted in a calm and rational manner as they attempted to find accurate information about the disease. Quoting directly from the CDC guidelines added to the credibility of the program. While we still have a long way to go to convince the public that these young patients are not a "menace to society," you have taken that all important first step. Prime time television programming can have a major influence on public opinion. Your episode represents responsible journalism at its best.

On behalf of our young patients and their families whose lives may be a little bit easier because of your show, and on behalf of my colleagues who give their all for these kids, I thank you for your very important contribution in the battle against AIDS.

Sincerely,

Deborah Rizzi

Deborah Rizzi
Public Realtions

DR/gds
Enclosures

cc: James Oleske, M.D.
Patricia Rickey, Producer

A MAJOR TEACHING AFFILIATE OF
THE COLLEGE OF MEDICINE AND DENTISTRY OF N.J. NEW JERSEY MEDICAL SCHOOL

Senator Kennedy's
Questions for Mrs. Helen Kushnick

1. Please describe the specific educational approaches regarding AIDS which the government might provide which you feel would be most helpful.

2. Do you feel that adequate steps are now being taken to safeguard the nation's blood supply?

ANSWERS:
Senator Kennedy:

1. A firm statement, based on the facts as known, that AIDS is not a casually contracted disease. Restating that the virus has been in the country for the past ten years and that if it were (casually contracted) half the country would be dead by now. Also, we need to stress the CDC on family transmission, e.g. 300 cases (attached to Nathan Smith's testimony) and no spread of the virus casually. Also, we need to educate the governors, mayors, boards of education and practicing physicians (thru the AMA). Essential that we work with the PTA. PTA is planning a meeting in Little Rock, mid June to issue a position paper. Also, essential that we start to educate the adolescent population (junior high and high school age as well as college level) with an effective film and workshop. AmFAR has located such a film in New York and we could use the government's help in funding and distribution. Information to the public must be done by the President.

2. No. The blood banking industry is an unregulated monopoly. Please refer to MONEY magazine article by ANDREA ROCK, March, 1986. I have met with Congresswoman Mikulski and Congressman Waxman regarding public witness hearings in Congress regarding the practices in the blood banking industry and decisions that are continually made on dollars involved rather than on safety. I would be happy to meet with Senator Kennedy regarding Senate hearings on this subject. HTLV-III testing is still not a law - as is the case with all other blood transfusion procedures. This industry sets its own rules. I was told today of a case in New York of the death of a child transfused nine months ago (from AIDS) - after the HTLV-III test was theoretically being used on all blood products. I want to examine the law which states that blood is not a product, but a service. A battlefield transfusion is a service - a directed donation (against the law in most states) for a family member is a service, taking one's own blood prior to elective surgery is a service, but taking blood from a donor and breaking it down into component parts and selling it into a world market is a product - not a service. And because of this law, this industry is allowed to set it's own standards. 20/20 (ABC) is currently putting together an investigative piece on the blood industry along the lines of the MONEY magazine article. (Joe Lovett - producer). If this industry is allowed to continue this self regulation the blood supply will continue to be sub=standard. Blood is the most dangerous drug you can get. Yet most physicians do not understand the risks involved with transfusions.

QUESTION FROM SENATOR HATCH

1) COULD YOU DOCUMENT FOR THE RECORD YOUR TESTIMONY THAT AS MANY AS 80 PERCENT OF PEDIATRIC AIDS PATIENTS ARE ABANDONED CHILDREN AND THAT THESE ABANDONED AIDS PATIENTS NUMBER IN THE HUNDREDS?

Senator Hatch:

I do not have the resources available to call the various states.
I have checked with United Hospital Medical Center in Newark.
They currently have approximately 45 pedicatric aids cases. More than 90% are IV drug user parents. They have been doing an effective job of obtaining extended care - foster, other family members, etc. for these children. However, most of the hospitals in New Jersey are either unable,or unwillingly, to deal with these children - so they have a patient population from as far away as a two hour drive to the hospital to be treated. When these children require nospitalizatio they are left. "Extended families" and/or foster care are tenuous situations at best, but with a handicapped child, expecially an AIDS child even more so.
Albert Einstein in New York (Bronx) currently has approximately 10 children living at the hospital.
Calls would have to be made to San Francisco, Florida and Texas as well.
One addtional note: The concensus among the physicians treating these children is that a lot are not being diagnosed. Again, about 80% over the next five years will be the product of the lower socio-enconomic, drug abuse population. There are some children who have survived for 5 to 7 years will AIDS. These children are unable to attend school - depending on the State. I also found out that in New Jersey, the

(over)

the Superior Court threw out the acceptance of the CDC guidlines approved by the Board of Education on the gounds that public witness hearings and due process had not been followed prior to their acceptance without commenting on the content of the guidelines. I am enclosing the statement from Elizabeth Kubler Ross to which I referred. I do think that the committee should contact her directly.

If I can be of any further help, please contact me.

To Live Until We Say Goodbye

Dr. Elisabeth Kubler-Ross

Dr. Elisabeth Kubler-Ross, internationally renowned physician, author and hospice pioneer asks you to join her in providing a home for abandoned children with AIDS. Currently, these children spend their young lives in the isolation of a hospital room with no hope — no hugs — no home. Abandoned by intravenous drug-user mothers who are emotionally, physically and financially unable to care for them, these little ones deserve a second chance. Won't **you** help bring them the gift of life and love?

FOR INFORMATION CALL OR WRITE

Dr. Elisabeth Kubler-Ross
AIDS Children's Home
South Route 616
Head Waters, Virginia 24442
(703) 396-3441

56

Bonus

INSIDE THE BILLION-DOLLAR BUSINESS OF BLOOD

Why blood bankers acted too slowly in protecting the public from AIDS

by Andrea Rock

In early December 1982, William V. Miller, the 42-year-old director of the American Red Cross' Blood Services for the Missouri-Illinois region, was summoned to a hastily arranged meeting at the National Library of Medicine in Bethesda, Md. The session had been called by officials of the U.S. Food and Drug Administration, the federal agency charged with regulating the nation's blood industry. That Miller would be invited to such a gathering was not unusual; an M.D., he was a member of the FDA's Blood Products Advisory Committee, a small group of industry and medical experts that meets quarterly with FDA officials to offer advice on regulatory matters. But an unscheduled meeting called on only one day's notice was unusual indeed.

Instead of gathering in the library's auditorium, where a formal committee session generally would be held, the members were directed to an adjacent conference room where a catered lunch had been laid out. In this informal setting, no minutes were kept. "That's how the federal government handles sensitive matters," says Miller. "We didn't meet, we just had a discussion over lunch."

It was hardly chitchat, however. While eating their sandwiches, the committee members listened to a presentation by Dr. Bruce Evatt of the Centers for Disease Control, the Atlanta-based federal agency that tracks clues about the spread of infectious diseases. In this case, the disease in question was acquired immune deficiency syndrome, already known by its now-familiar acronym of AIDS. The immunological disorder had been a CDC concern since 1981 and, as far as its researchers knew, was fatal in at least 60% of the cases.

Evatt began by offering data from CDC investigations of several unusual cases of AIDS. In each of them, the victims were not homosexual men, intravenous drug users or members of any other group known at the time to be at high risk for the disease. But they did have one thing in common: they had received blood transfusions or had used a blood-based product within the previous five years. Could it have been a coincidence? In tracing back through blood bank records to identify the donors of blood transfused to the AIDS victims, CDC investigators had discovered that each case had a common factor: at least one of the donors was in an AIDS high-risk group or had developed the disease. This evidence pointed strongly to one conclusion. Whatever was causing AIDS was an infectious agent, probably a virus, and it had begun to contaminate the nation's blood supply.

Miller was stunned. Until then, he had been skeptical about the fragmentary evi-

PHOTOGRAPH BY JACK REZNICKI

dence that AIDS could be spread through blood. No longer. Recalls Miller: "I now thought the evidence was clear that AIDS was spreading more rapidly than I had appreciated, that at least some of it was being spread through blood, and that we were facing one hell of a public health problem."

This is a story about blood, the most precious fluid on earth. Each of us has about eight to 12 pints of it; lose more than a third of your supply suddenly and your chances for survival are slim. More specifically, this is a story about the business of blood. It is a paradoxical business, a billion-dollar-a-year enterprise that is not for profit. Sometime in your life you may come into intimate contact with it. Roughly 3.5 million Americans had transfusions last year. When you or a member of your family needs one, you will be grateful indeed that safe blood was available.

The supply and distribution of blood in America is dominated by an institution only slightly less revered than apple pie: the American Red Cross. Each year its 57 regional centers collect half of the nation's 12 million one-pint units of donated blood. Regional and community blood centers and hospital blood banks collect the remainder. The task of collecting the annual blood supply—an amount sufficient to fill three Olympic-size swimming pools—is carried out almost exclusively by not-for-profit organizations.

But when the task at hand was alerting the public to what was known about the contamination of the blood supply with AIDS, and then acting to protect the safety of that supply, the blood industry moved with tragic slowness. In handling the AIDS crisis, the blood bankers:

- Refused initially to accept evidence that AIDS could be transmitted by transfusion and then downplayed the risk when they finally admitted it existed.
- Delayed the implementation of active screening procedures designed to discourage blood donations from people in AIDS high-risk groups.
- Resisted the use of surrogate blood tests that could be used as stopgap measures to reduce risk until a more specific AIDS screening test became available.
- Made and continue to make exaggerated claims about the current screening test's ability to identify AIDS-contaminated blood.

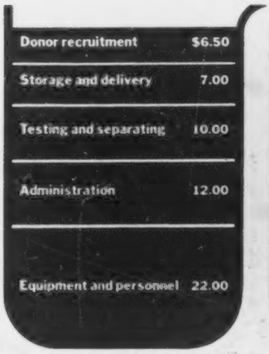
Because of such resistance and delays, a still unknown number of people who received transfusions in recent years may carry the AIDS virus and thus are now at risk for transmitting and possibly being struck by the disease. "In their resistance, blood banking leaders made a fatal error," says Arthur Ammann, a San Fran-

Reporter associate: Martha J. Mader

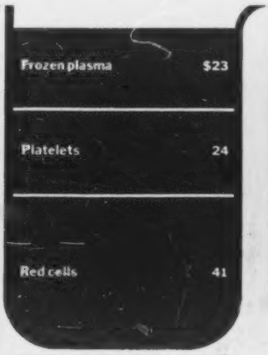
Adding up the price of a pint of blood

Blood banks receive blood free from donors but incur expenses in collecting, processing and delivering it to hospitals. The left beaker shows a breakdown of those costs at a blood bank in the Midwest. The blood bank recovers its expenses through fees it charges hospitals for each unit of blood. Typically, units are separated into components that are sold individually for total fees exeeding collection costs. The beaker in the center depicts charges for a typical combination of components that would be delivered to a midwestern hospital. Nationwide, fees vary greatly. The charge for a unit of red cells, for example, ranges from $33 in Mobile to $68 in San Jose. If the pint were sold as whole, unseparated blood, it would bring the blood bank an average fee of only $42.

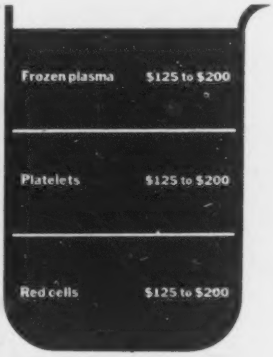
The beaker at right represents revenue the hospital will receive once the components are transfused to patients. Most likely three patients will be treated with—and pay for—components that come from one pint of blood. Hospitals' charges reflect a 326% to 582% markup on their cost for blood to cover lab fees, profit, and personnel and equipment required to give transfusions.



What blood costs to collect Total: $57.50

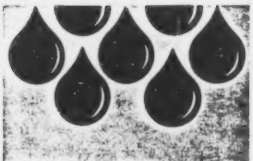


What blood costs hospitals Total: $88



What blood costs patients Total: $375 to $600

ILLUSTRATIONS BY JAVIER ROMERO



AIDS and the blood supply: Who did what when

- **1978:** First AIDS-like illnesses reported in U.S.; disease not positively identified until June 1981.
- **July 16, 1982:** Centers for Disease Control publicly reports first three cases of AIDS in hemophiliacs.
- **Dec. 4, 1982:** CDC presents Blood Products Advisory Committee with mounting evidence that AIDS is being spread through blood supply. No action is taken.
- **Jan. 14, 1983:** National Hemophilia Foundation asks blood and plasma collectors to adopt screening procedures to discourage donations from high-risk groups—specifically homosexual men; commercial sector complies, but blood banks continue to accept blood from all donors.
- **March 4, 1983:** U.S. Public Health Service announces that high-risk groups shouldn't donate. Blood-banking organizations notify members March 7.
- **March 24, 1983:** FDA issues donor screening guidelines, which some blood banks had begun to implement.
- **Jan. 12, 1984:** The New England Journal of Medicine publishes CDC documentation of first 18 transfusion-associated AIDS cases. Blood banks continue only to screen donors.
- **March 6, 1984:** Industry task force meets on surrogate testing. Blood bankers oppose the procedure; commercial collectors plan to test.
- **April 23, 1984:** Secretary of Health and Human Services Margaret Heckler announces discovery of virus believed to cause AIDS; says test to identify contaminated blood will be available in six months.
- **March 2, 1985:** FDA approves first AIDS antibody screening tests. Nationwide testing begins.
- **Feb. 3, 1986:** Reported AIDS cases total 17,001 (449 traced to use of blood or blood products); 8,801 people have died to date.

cisco physician who reported the first case of AIDS that the CDC viewed as clearly tied to transfusion. "Unfortunately, patients who received transfusions became the proof of whether they were right or wrong." At least 36 AIDS cases have been linked to transfusions administered *after* the CDC had alerted the blood industry at the Bethesda luncheon session to the gathering evidence that its product was implicated in spreading a fatal disease.

In four months of investigation, *Money* has examined the inner workings of the billion-dollar-a-year, not-for-profit blood business. We spoke to scores of federal officials and industry leaders, including top executives at the Red Cross, analyzed thousands of pages of scientific documents and transcripts of meetings between government and industry representatives and reviewed press accounts of public statements affecting the blood banking industry.

What emerges is a portrait of an industry that has succeeded at one-half of its responsibility—to maintain an adequate blood supply—but has failed at the other—to make that supply as safe as possible. The problem is that building an ever-increasing supply of blood feeds the industry's revenues, while taking steps to make blood safer or to reduce unnecessary transfusions does not. "There are very few economic incentives for the blood industry, which is a pure cartel, to push conservation of its product," says Dr. Bruce Friedman, professor of pathology at the University of Michigan Medical School. "Blood suppliers are looking at the bottom line." Gilbert Clark, director of the American Association of Blood Banks (AABB), a trade group, describes the major players somewhat differently. Under new cost pressure that forces them to compete with one another for contracts to supply hospitals with blood, Clark says blood banks are "no different from Ford going after Chrysler."

As he left the Bethesda meeting on that rainy day in December 1982, William Miller, now convinced that AIDS was bloodborne, was in a minority among his colleagues. Despite the alarming evidence revealed by the CDC's Bruce Evatt at the luncheon briefing, the FDA's Blood Products Advisory Committee wanted more proof. Thus the group made no recommendation public or private to respond to the news that the nation's blood supply could be the route for the spread of a fatal disease. In fact, most blood bankers, including top officials at the American Red Cross and leaders of the two main industry trade groups, the AABB and the Council of Community Blood Centers (CCBC), insisted publicly throughout the following year that the evidence linking AIDS and blood was still inconclusive. More than a year after Evatt presented his evidence to Miller's group, New York Blood Center president Aaron Kellner said during a panel discussion at the CCBC's February 1984 annual meeting: "We're not convinced that AIDS is transmitted by blood transfusion. . . The evidence is still very shaky."

In retrospect, Miller acknowledges that "there was a fair amount of denial and foot-dragging going on in the blood community." He attributes that to a common human reluctance to "face up to an unpleasant reality."

The reality is even more unpleasant than anyone could have guessed in 1982. So far, 2.6% of America's more than 17,000 confirmed AIDS cases have been traced to the use of blood or blood-based products, including one in particular—the so-called clotting factor, which hemophiliacs inject to stem uncontrolled bleeding. To date, around 300 cases of transfusion-associated AIDS have been reported in the U.S., plus 149 among the nation's 20,000 hemophiliacs. Those numbers may only hint at the true extent of the problem. CDC officials now estimate that the average time between transfusion with AIDS-contaminated blood and diagnosis of the disease is five years, rather than two years as they had originally thought. Thus, most of the AIDS infections caused by transfusions given after mid-1981 have yet to be discovered. More than 65% of U.S. hemophiliacs have been exposed to the AIDS virus; how many of them will develop the disease is unknown.

At least 15 multimillion-dollar lawsuits have been filed thus far on behalf of hemophiliacs or transfusion-associated AIDS victims, most of whom have died. Some of the suits—filed against blood banks, hospitals, physicians and manufacturers of blood derivatives—challenge state laws giving the blood industry special protection against liability actions. These statutes classify providing blood as a service rather than as the sale of a product. The effect is that, unlike other businesses, blood banks and companies manufacturing blood derivatives cannot be held liable for injury resulting from blood or derivatives unless negligence can be proved. Many plaintiffs in AIDS lawsuits have alleged that blood bankers and derivatives manufacturers were in fact negligent, primarily for failing to reject donors at high risk for AIDS.

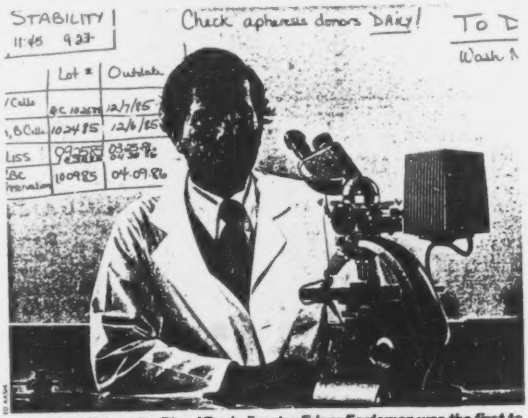
The banking of blood—that is, taking it from a donor, storing it and supplying it to a recipient later—has been possible since early in this century. Until that time, blood could only be transferred directly from one human being to another. During World War I, refrigeration and the addition of a chemical compound to prevent blood from clotting made blood storable for up to 14 days. Further scientific advances have now extended storage time to 42 days, and the FDA allows red cells, the blood's oxygen-carrying components, to be frozen for as long as three years.

During World War II, the American Red Cross opened 35 donor centers in the U.S. to collect blood, primarily for the military. Immediately after the war, the Red Cross shared the civilian blood-collection business with hospitals and regional medical societies. But when civic groups increasingly asked local Red Cross chapters to provide blood-banking services, the national organization saw in the requests a duty—and an opportunity. The Red Cross, says the AABB's Gilbert Clark, "woke up and smelled the coffee, realizing they could have had it all."

Clark is not an unbiased observer. The organization he heads was formed in 1947 to protect the interests of then-existing blood banks threatened by the Red Cross' announced plan to collect and organize the nation's entire blood supply. The AABB now has 2,400 members, most of them hospital and community blood centers. The other trade group, the Council of Community Blood Centers, has 31 members, of which most are regional blood banks. Along with community blood centers, they are the Red Cross' most significant competitors. They collect 39% of the nation's blood supply; hospital blood banks 11%.

Like the Red Cross, members of the CCBC and all but a few AABB members are not-for-profit organizations. This means that they've met Internal Revenue Service requirements qualifying them for tax-exempt status. These tax-exempt blood collectors are referred to in the industry as the voluntary sector, because they take donations from unpaid volunteers only. There is, however, a separate sector of the blood industry that is for profit. In this commercial sector are companies that collect plasma, the yellowish liquid that remains when the oxygen-carrying red cells and other solid components are removed from blood. Its donors are paid, customarily about $10 per donation, because the plasma-collecting process requires two to three hours—more time than most people are willing to volunteer. These commercial concerns either manufacture the plasma into derivatives or simply sell the plasma to firms that do. This side of the business, dominated by subsidiaries of pharmaceutical giants Baxter-Travenol, the West German firm A.G. Bayer, Revlon and Green Cross of Japan, has annual revenues of more than $1.5 billion.

In entering the civilian business after World War II, the Red Cross unquestionably found a substantial revenue generator. Profits for tax-exempt corporations are called excess of revenues over expenses, and in the blood business they can be substantial. In the fiscal year ended June 30, 1985, the Red Cross' Blood Services had $41.2 million in these not-for-profit excesses before property and equipment acquisitions; total revenues were more than $466 million.



Stanford University Blood Bank director Edgar Engleman was the first to take action to screen blood, not just donors.

If Blood Services were a for-profit corporation, its fiscal 1985 revenues would place it in the Fortune 500 at position No. 473. Its 8.8% excess of revenues over expenses for that year would put it in a tie with Philip Morris for 50th place among Fortune 500 firms in terms of net income as a percentage of sales. Other blood banking organizations are generally profitable, though on a smaller scale. In referring to the volunteer groups, including the Red Cross, the AABB's Gilbert Clark says: "Think of us as tax-exempt rather than not-for-profit. We have to make a profit."

In the Red Cross' case, where do those excess funds go? Not to research. Only about 2% of Blood Services' annual budget is spent on that. Nor do they go to the other worthy charitable functions the Red Cross performs, such as disaster relief. Those excess revenues sometimes don't even go for Blood Services' own expansion: the Red Cross is seeking public donations to fund a planned $17 million research facility in Rockville, Md. Rather, the surplus goes to a balance-sheet category called accumulated net assets. As of June 30, 1985, they totaled $187.5 million. Of that sum, $87.4 million was in cash and investments—primarily interest-bearing government securities—and $54.9 million was in accounts receivable, which are considered easily convertible into cash. The remainder was in inventory and other assets.

After reviewing Red Cross Blood Services' financial records for fiscal years 1980 through 1985 at *Money*'s request, Sidney Shainwald, a C.P.A. and former chief financial officer of Consumers Union, another not-for-profit corporation, concluded: "This is a very rich organization. If it were public, I'd love to own stock in it." In response, Victor W.

Schmitt, vice president of medical operations for the American Red Cross, says: "I don't believe in any way that our revenues or our assets are inappropriate for the job we have to do."

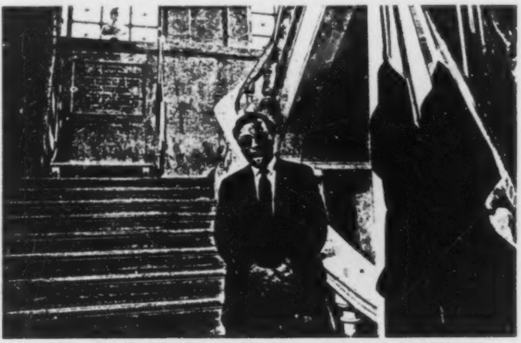
Part of the reason for the blood industry's robust financial health, and for that of Blood Services in particular, can be traced to a shift in the method of distributing blood that began in the late 1960s. Instead of handling what is known as whole blood, the bankers began to separate a unit of blood into its components, so physicians could give each recipient the part of blood that he or she required. From 1971 through 1980, whole-blood transfusions declined from 67.4% of total transfusions to only 13%. This switch to what is known as component therapy conserved supply. But it also enabled blood banks to take one unit of blood and produce two or more components that they could sell for a higher total than the price they could get for a single unit of whole blood. It's also higher than the cost of collecting that unit. (See the box on page 154.)

Many blood banks increase revenues further by selling plasma to the for-profit sector of the industry. The Red Cross and the New York Blood Center, however, go one better. The New York Center has its own plant to manufacture derivatives. The Red Cross has a contractual arrangement with a Baxter-Travenol subsidiary, Hyland Therapeutics, whereby the company manufactures Red Cross plasma into derivatives that carry the Red Cross label. Both the New York Center and the Red Cross then sell their products in head-to-head competition with commercial manufacturers such as Revlon's Armour Pharmaceuticals. Sales of plasma derivatives now account for about 15% of the Blood Services' annual revenues and 23% of the New York Center's.

In this sideline, the Red Cross and the New York Center have several competitive advantages. They do not pay taxes, nor do they pay fees to blood donors. Such fees represent 30% of production costs for the commercial companies.

Another edge that the Red Cross makes ample use of: donor-recruitment ads, run free of charge across the country as a public service in print and on TV and radio. The Red Cross' current campaign has been designed by the world's largest advertising agency, J. Walter Thompson, which does not bill the Red Cross for its creative services. In 1984 the total value of pro bono publico services given to the Red Cross for its blood-program advertising amounted to some $21.3 million.

These advantages, however, do not result in bargain prices for Red Cross derivatives sold to hospitals and hemophiliacs. (A victim of hemophilia typically must spend $4,500 to $13,000 a year for clotting factor alone.) "When the Red Cross competes in the marketplace, it charges within pennies of what the commercials do," says Robert Reilly, director of the American Blood Resources Association, a trade group for the commercial side of the blood business. The Red Cross' Victor Schmitt avers that while there are occasions when Red Cross derivative prices match those of commercial producers, "our prices are, on average, lower."



Gerald Sandler, Red Cross associate vice president for medical operations, says blood bankers have done all they could to protect the supply.

Hospital administrators have always regarded blood as a commodity they must stock along with supplies such as floor wax. But there has been one important difference: the price the hospital pays for blood could be passed along in full to patients or their insurers. There was no incentive to shop for the low-cost supplier as there would be for floor wax, the cost of which the hospital must absorb or pass along in administrative fees.

Now, however, a new reimbursement system that rewards hospitals for cutting the cost of treating a patient is spreading through the health-care system. The hospitals' costs of obtaining blood can no longer be passed directly to Medicare patients or to any of the increasing number of others covered by such payment systems. Thus hospitals are for the first time pressuring blood banks to lower fees.

The results are already evident in the marketplace. Last February the University Medical Center in Tucson, which had relied on the Red Cross as its blood supplier, invited bids from UBS, a not-for-profit corporation based in Scottsdale, Ariz. that is a tenth the size of the Red Cross. UBS offered to supply the center with red cells (the standard for price comparison in the industry) for $34 a unit, compared with the Red Cross' fee of $53.35. The hospital snapped up the deal, which cut its costs by $250,000 annually. The Red Cross reacted by cutting its fees in the Southern Arizona region to match the UBS price—and thereby protect its business with other area hospitals.

From a business standpoint, then, the AIDS problem could not have hit the industry at a worse time. While blood bankers are under growing pressure to cut costs, AIDS testing and donor screening have added to their expenses. Many centers have passed on the added costs of testing to hospitals by means of surcharges of 2% or more. The Detroit-area Red Cross, for instance, added a $2.25 testing surcharge to its $39 fee for a unit of red cells. Other blood-banking groups, such as UBS, have absorbed the cost with no increase in fees. Then too, the mere possibility that lawsuits filed by AIDS victims could remove the industry's unique shield from liability has made many blood bank insurers so nervous that during 1985 they more than doubled—in some cases quadrupled—the banks' liability insurance premiums. These higher costs have not been passed on as yet.

Even before AIDS, the blood industry had been faced with another major transfusion-transmitted disease risk. The villain was hepatitis, the liver ailment, and on occasion the industry's debates over how to respond to that threat have paralleled those that have taken place with respect to AIDS. Since 1972 all donated blood has been routinely screened to detect the hepatitis B virus. At about the same time, blood bankers shed their reliance on paid donors because studies had shown that such donors often included intravenous drug users and others at high risk for hepatitis. Even so, an estimated 7% to 12% of all transfusion recipients develop hepatitis. Most of them are now believed to suffer from another form of the disease, caused by a yet unidentified virus. Researchers estimate that as many as 19,000 severe illnesses or deaths may be attributed each year to this peculiar transfusion-transmitted hepatitis.

Two different blood screening tests that may reduce the risk of hepatitis exist and are used by scattered, individual blood banks. One is called the core antibody test; it indicates past exposure to hepatitis B. The other is called an ALT test. It detects a liver enzyme that circulates in large amounts through the blood when the liver has been damaged, as in hepatitis. No national agreement has been reached for routine use of either test, though both have been the subject of industrywide debate for the past five years or so. The debate centers on cost-effectiveness: Are the tests reliable enough to justify the $2.50 to $5 per-unit costs of performing them and the 2% to 5% loss of donors whose blood would probably be rejected as a result of the testing? This debate over hepatitis testing was temporarily sidetracked when the AIDS crisis hit.

In early 1983, just six weeks after the CDC presentation that persuaded William Miller that blood was a culprit in spreading AIDS, National Hemophilia Foundation officials acted on their conviction that AIDS was being transmitted to hemophiliacs through the clotting factor. It is manufactured from batches of plasma pooled from hundreds of donors; just four AIDS carriers who donate plasma frequently can contaminate an entire year's output of the substance. At a meeting in New York City on Jan. 14, 1983, the medical and scientific advisory council of the NHF presented its recommendations to public health officials and blood industry representatives. They asked that all blood and plasma collectors begin procedures to discourage donations from homosexual men and others in high-risk groups.

The commercial plasma collectors went along with the screening idea immediately. (Hemophiliacs, whom the NHF represents, are an important market for derivative manufacturers.) But the Red Cross, the American Association of Blood Banks and the Council of Community Blood Centers resisted the proposal.

Representatives of those three groups were worried about charges of invasion of privacy that might result from attempts to limit donations from homosexuals and other high-risk groups. They argued in a joint statement to their members that the NHF recommendations were premature. The blood bankers said "evidence that AIDS can be spread by blood components remains incomplete."

The voluntary sector, concerned about maintaining an abundant blood supply, also worried that the public might well confuse the screening of blood donors with the very real dangers of receiving contaminated blood. That worry about public misperception proved correct. A recent survey conducted for the AABB revealed that one in every three Americans still believes that AIDS can be contracted by donating blood. That belief is mistaken.

At the time the NHF issued its warning, eight cases of AIDS had been documented in hemophiliacs. Ten involving transfusion recipients were under investigation. Recalls NHF director Alan Brownstein: "Hemophiliacs serve as an early-warning system for the safety of the blood supply. The message we were trying to communicate at that meeting was that we were blinking a yellow warning about the blood supply, and we didn't want the industry to wait for a red light to take action."

In fact the Red Cross, AABB and CCBC did not act to discourage high-risk groups from donating until two months later. Even then their response came not so much voluntarily as in reaction to a U.S. Public Health Service advisory that high-risk groups shouldn't give blood. That advisory was followed a few weeks later by FDA guidelines recommending that all blood banks begin providing donors with educational material describing who could be considered at risk for AIDS and then asking people who met the description not to donate. In the interim, from January to March of 1983, more than 1.5 million units were collected. No one knows how many of those units were contaminated with AIDS and were later given to unsuspecting recipients.

In the spring of 1983, even as the rest of the blood-banking industry was putting into place the new donor screening procedures, Stanford University Blood Bank director Dr. Edgar Engleman concluded that simply asking high-risk groups not to donate wasn't sufficient. He believed that blood, not just donors, should be screened. The problem, though, was that no test could specifically detect AIDS. The virus believed to cause the ailment hadn't been discovered yet.

The alternative was to find a test that could be used as a surrogate—one that would identify a characteristic found in the blood of AIDS victims or those at high risk for carrying the disease. Public health officials were evaluating several such tests at the time, but Stanford chose one called the T-cell test, which it began using on July 1, 1983. The test detected an abnormality often seen in a type of blood cell, the T-cell, of AIDS victims and others suffering from viral infections.

The cost of testing forced Stanford to raise the fees it charged hospitals by roughly 10%. The price of a unit of red cells, for instance, increased from $60 to $66. Patients who ultimately were footing the bill voiced no objections. But blood bankers in the San Francisco area 30 miles north of Stanford and elsewhere criticized the test as being too costly, particularly since its effectiveness had not yet been proved beyond doubt. Some also accused the Stanford blood bank, which serves the university's hospitals and another in the area, of adding the test in an effort to steal business. In a city having the nation's second highest AIDS rate per million (New York City is first), hospitals were sensitive to patients' fears about the disease. Says Engleman: "I can understand the hostile reaction we received. If we were testing blood and they weren't, either they were irresponsible—which is a mild word for it—or we were."

While Engleman says he didn't intend for surrogate testing to become a marketing tool, it became just that. Citing public demand for testing and pressure from physicians whose patients had elected to have surgery at Stanford rather than in San Francisco hospitals, Brian McDonough, director of the Irwin Memorial Blood Bank, supplier to 40 Bay-area hospitals, announced in May 1984 that his center would begin surrogate testing. Irwin, however, opted for the core antibody test that blood bankers had been considering to reduce hepatitis risk. A January 1983 CDC study of AIDS victims had found that the substance the core antibody test detects was present in 88% of homosexual patients, in 100% of intravenous drug users and in only 5% of the non-AIDS-patient control group.

A month after Irwin began testing, the San Jose-based Red Cross Blood Services region followed suit. Its medical director, J. Lawrence Naiman says "competitive pressure from other blood banks in the area" was partially responsible for his center becoming the only Red Cross region to adopt surrogate testing. As a result, the center imposed a surcharge of $4 on every blood component it sold.

Because of AIDS' average five-year incubation period, the definitive report card on surrogate testing's effectiveness is years away. But circumstantial preliminary data argue in its favor. No AIDS cases have yet been reported involving blood from any of the three blood banks since testing began at each. Nine cases have been linked to 1984 transfusions of blood from blood banks that were relying solely on donor screening procedures throughout that time.

In the months after Stanford began protecting its blood supply, the three major players in the voluntary sector—the Red Cross, AABB and CCBC—maintained their official stance that routine, nationwide surrogate testing was not warranted. The topic was the subject of much internal debate, however. In December 1983, for example, five months after Stanford had begun surrogate testing, but four months before the Irwin blood bank would, Dennis Donohue, an M.D. and director of the blood and blood-products laboratory at the FDA, suggested to the Blood Products Advisory Committee that the industry consider adopting the core antibody test. Once again, with representatives from the so-called voluntaries vocal in opposition, the industry panel avoided a decision, opting instead to form a task force to study the issue.

When the task force convened three months later, in March 1984, opinion was split. It was divided just as it had been on the issue of donor screening: the voluntary sector opposed testing, while the commercial side, needing to maintain the confidence of hemophiliacs, advocated it.

The voluntary sector's primary objections were familiar ones: that the test would not be cost-effective and its reliability had not been proved. The blood bankers estimated that testing would cause them to reject precious blood collected from 3% to 10% of donors, not all of whom would necessarily be AIDS carriers. They calculated that testing would add $12 to the cost of collecting a unit of blood. The bulk of that cost, the blood bankers said, would reflect the expenses of discarding already-collected blood and recruiting additional donors to replace that blood. Finally, they argued that donor screening guidelines already in place were more effective in excluding high-risk donors than the test would be. The task force recommended no action.

The commercial collectors, however, were planning to go ahead with core antibody testing no matter what the voluntary side of the business did. This put pressure on the not-for-profits, especially if they wanted to continue selling plasma to commercial manufacturers. The squeeze didn't last long, however.

On April 23, 1984, Margaret Heckler, then Secretary of Health and Human Services, called a press conference to announce that the virus believed to cause AIDS had been identified by a research team headed by Dr. Robert Gallo of the National Institutes of Health. Within about six months, she said, a test would be widely available that could "identify AIDS victims with essentially 100% certainty."

Secretary Heckler was wrong on both counts. Nearly a year passed before a test was on the market, and by no means was it capable of identifying all AIDS carriers. The promise of its availability in only six months, however, eliminated pressure on blood bankers from the public and from the commercial sector to do surrogate testing. In that time, about 10 million pints of blood were collected.

The test now in use reveals whether a blood sample contains specific antibodies that the body develops to fight the AIDS virus, thereby indicating that a donor has been exposed to it. Thus, because it is what researchers call specific to AIDS, it is better than a surrogate test.

CDC officials do not know how many people who have the antibodies will go on to develop AIDS. They presume, however, that anyone with the antibodies or the virus itself is capable of transmitting the disease to others. They also believe that such a person may remain infectious throughout his or her lifetime.

As for the question of certainty, unfortunately the antibodies that the test measures may not appear in blood for 11 months after infection with the virus. Equally troubling is that an unknown percentage of AIDS carriers, believed to be small, may never develop detectable antibodies. A study conducted by researchers at the National Cancer Institute and the Pennsylvania State University School of Medicine in Hershey revealed, for instance, that six apparently healthy wives of hemophiliacs, out of a group of 10 being studied, carried the AIDS virus. The virus, which the women apparently picked up through sexual relations with their AIDS-infected husbands, was detected by means of a complex, not readily available procedure. The AIDS screening test showed no signs of antibodies in the women's blood for up to 11 months after they had been confirmed as carriers of the virus. A similar U.S. study published in the British medical journal Lancet in December 1984 revealed that four out of 96 people in whom the virus had been detected displayed no symptoms of the disease and would have slipped through the AIDS antibody test because they had no detectable antibodies.

Given this evidence of the test's limitations, many blood bankers and public health officials have inaccurately reassured the public about the test's ability to screen out contaminated blood. For example, Dr. Harry M. Meyer, director of the FDA's Center for Drugs and Biologics, publicly proclaimed last July that the AIDS antibody test "is picking up essentially every potentially infectious unit of blood."

The true measure of the test's effectiveness will be the number of people who develop AIDS from blood collected after testing began in March 1985. No cases have yet been reported. But because the average incubation period for transfusion-associated AIDS is so long, the final judgment is years away.

Max Essex, chairman of the cancer biology department of the Harvard School of Public Health and a member of the research team whose work was crucial in developing the AIDS antibody test, is one of the most vocal critics of those who exaggerate its effectiveness: "I'm not saying the test we have now should not be used or that it hasn't greatly cut the odds of contracting AIDS through transfusion. But I'm afraid these overly optimistic statements that are being made about the safety of the blood supply will eliminate public pressure to develop better tests." Dr. Alfred Katz, the Red Cross' vice president for research and development, agrees that a better test is needed. In testimony last summer before a Senate committee on AIDS research funding, he said that the test has "theoretical and practical defects" and that "it is essential that we develop a test that directly identifies infective blood."

Gerald Sandler, the Red Cross' associate vice president for medical operations, acknowledges that the AIDS antibody test is not perfect. But in an interview with *Money*, he argued that its limitations don't seriously jeopardize the blood supply's safety. He says that the so-called asymptomatic AIDS carriers identified in the Lancet study and others as having been missed by the AIDS antibody test are members of high-risk groups. Thus, he says, they "aren't people who are eligible to donate." Sandler maintains that the safety of the blood system begins with the assumption that volunteer donors are healthy people who have passed the donor screening process. Blood tests such as the AIDS antibody test, he says, serve merely as a backup.

But the fact remains that high-risk donors, whatever their motivation, continue to donate. Blood bankers circulate the story among themselves of a donor implicated in a transfusion-associated AIDS case who, when traced by the CDC, turned out to be the chairman of his company's blood drive. Though he was a homosexual, he felt pressured to donate. In another such case, the infectious donor was a woman who did not consider herself in a high-risk group because she had experimented only once with intravenously administered drugs five years prior to donating. The number of units of blood that are discarded because they register positive on the AIDS antibody test, an estimated 14,400 in the Red Cross system alone in the first year of testing, is further evidence that people who should not donate do so anyway.

Then too there is at least one group of potentially high-risk donors whose members aren't asked to refrain from donating: individuals, and the sexual partners of individuals, who have had transfusions since the AIDS crisis began. The FDA's Dennis Donohue says the inclusion of that group among high-risk donors has been discussed among FDA and Public Health Service officials but no decision has been reached. "Considering the tremendous anxiety that surrounds AIDS," he asks, "if I were to tell everyone who'd received a transfusion since 1978 that they were in a high-risk group, would I truly be performing a public service?"

Reluctance to feed public hysteria about AIDS is a reasonable concern. But the better question to ask now is: What steps can be taken to improve the safety of the nation's blood supply? First, post-1977 transfusion recipients and their sexual partners should be added to the list of AIDS high-risk groups who are asked not to donate blood. Though doing so would call attention to a sensitive area for the blood industry, it would nonetheless help ensure that potentially infectious blood does not enter the system. Such disqualified donors should not be overly difficult to replace. Only 5% of eligible donors give blood now. Thus there is a large, untapped pool of non-high-risk potential donors from which to draw.

Second, the blood industry must not compound its initial reluctance to admit that a problem existed by being overeager to imply that the problem of transfusion-transmitted AIDS is solved. Armed with an accurate assessment of the risks associated with transfusion, patients scheduling elective surgery can consider alternatives such as autologous donation—stocking their own blood before surgery. This is always considered the safest form of transfusion. Most blood banks offer this alternative, though some may impose a surcharge of a few dollars per unit. Patients usually must ask their physicians to put in an order for autologous donation at the local blood bank, and patients must be healthy enough to withstand the donation process, which typically requires giving three pints of blood in the month prior to surgery.

Third, greater effort must be devoted to educating physicians on the risks involved in transfusion, to monitoring the use of blood components and to researching transfusion-transmitted infections. The University of Michigan's Bruce Friedman says that 25% of red cell transfusions are unwarranted. "The standard medical school curriculum provides inadequate training in the proper uses of transfusion and its risks," says Friedman.

Special attention should also be given to updating physicians on transfusion risks that may have emerged since they were trained. One such complication that has been identified recently is blood-borne cytomegalovirus (CMV), which can be fatal to premature babies and a danger to cancer or transplant patients. This risk can be greatly reduced if doctors request blood for such patients that has been tested and found free of the virus. Units of CMV-negative blood usually carry a surcharge of $10 or less each.

Fortunately, both the hepatitis and AIDS experiences have made patients and physicians more aware of transfusion's risk. This, combined with a more cost-conscious approach toward blood supply, is leading to more conservative use of blood components. Friedman forecasts that demand for red cells will decrease 3% to 5% annually over the next five years or so.

Such downward pressures on the price of blood may be more than offset by higher liability insurance costs and the increased cost of any additional tests that are adopted. The industry now is considering adding the core antibody test, not only to reduce the risk of hepatitis but also to serve as a backup for the AIDS test. Doing so would add about $4 to the cost of each blood product.

Costs certainly must be weighed against potential benefits when making decisions about ways to improve the safety of the blood supply. But fresh thought must be given to how those decisions are made. Consumers of blood suffer the consequences when available steps to reduce risk are not taken, and they—or their insurers—also foot the bill when safety measures increase costs. Yet their voices are seldom heard in the decision-making process. The question the public deserves to be asked: Would you be willing to pay more for blood if that extra cost covered procedures that could make blood safer?

Says Dr. Joseph Bove, chairman of the AABB's transfusion-transmitted diseases committee and director of the Yale–New Haven Blood Transfusion Service: "Concerns about cost and a shrinking donor base are valid, but they must not be allowed to control the decision-making to a point where measures with a proven, or even a highly probable, benefit are not implemented. The American public expects and should have the safest blood available. To provide less, even in a cost-conscious society, is unacceptable."

The CHAIRMAN. I think all of you have added a great deal to this hearing by your statements. I want to compliment you on the excellent testimony that you have given to us.

Let me begin with you, Mr. Smith. I think it has taken great courage for you to come and to share your experiences with us. In that regard, you are an inspiration to all of us, and we personally appreciate it.

Let me ask you a few questions. As a hemophiliac, and reliant on receiving blood products at periodic intervals, are you convinced that our Nation's blood supply and blood products are presently safe for you and other hemophiliacs?

Mr. SMITH. As a matter of fact, I am. And I guess the most convincing part about that is when I was lying in the hospital and discovered that a blood bag was being hung above me because I was going to receive a blood transfusion due to some interactions with the drugs I was then using, my first thought was, when I saw that blood bag, that that is not heat-treated product, it is not like the concentrate, and I have a risk of getting AIDS if I have that transfusion. And I think that, yes, we can screen the antibody out, and we can do greater donor selectivity, and for some products, such as heat-treated hemophilic therapeutic products, we can inactivate the HTLV-III virus that is there. And for those people who use those products, from what I can understand and from what I feel, I think there is no risk at all.

I have brought with me in my briefcase some transfusion products should I have a hemorrhage, and in the hotel this morning I could have transfused, and I would have, without any difficulty or question about it being safe.

I cannot speak for other blood products that other people may use that are not subjected to heat treatment and for which there is no other method of screening out the AIDS virus.

But I am confident that at least the hemophiliacs have a much safer future than they did a few years ago, before we knew much about AIDS.

The CHAIRMAN. Thank you.

You and your family and apparently most of your friends have adopted what I consider to be sensible attitudes about AIDS transmission, based upon existing guidelines.

What can our Federal Government do to ease the lingering public fears about the spread of AIDS and the contraction of AIDS around the country?

Mr. SMITH. In my State, we had hysteria for a while concerning the quarantine issue, and it turned out that there was much misinformation. The decisionmakers on these issues turn out not to be professionals in the public health department or Senators, but they turn out to be schoolboard members who do not know anything about AIDS; they turn out to be Governors, who also do not know a great deal about it from all that I can tell, because of some statements that have been made by certain Governors. They turn out to be people at every level in employer-employee relationships, even in some public health areas, where AIDS to them is a fear.

One of the things that I think could be done is to make an attempt to talk to these decisionmakers directly. For instance, there are only 50 Governors in the country, and they all get together once or twice a year with the National Governors Conference. Why not delegate a CDC representative to present a little briefing book to each of the Governors there and spend an hour making sure that they are fully aware that all scientific evidence is current; and that then, when they go back to their States, they can act responsibly, based on that information.

Another possibility, we have—I do not know what the total number is in this country, but it cannot be more than 20,000, 30,000, 40,000 schoolboard members. Why not make a direct mailing to every schoolboard member in this country and alert them with the actual facts that we know about AIDS and education, so we do not have Ryan White waiting outside school for a judge to make a decision, or we do not have the difficulty of parents forcing schools to take positions that they otherwise might not take because of lack of information.

I think we could take a look at the hospice guidelines that the Federal Government has. They are intended for people who are projected to have 6-month lifespans. What if you are a person with AIDS, and you have no immediate family, and you suffer from the stigma of having difficulty finding people to help you, and you have a projected life that might be 6 months, it might be 2 years. What do you do, and how can you possibly be reimbursed with the limitation as it is currently set up under AIDS hospice regulations, under Medicare Reimbursement Programs?

I will tell you another one. Mrs. Kushnick referred to the problem of how you get effective treatment. When I was in the hospital in November, I was assured that the hospital was very close to announcing an experimental program involving treatment for the disease, and that it was only a matter of days before I could be enrolled in this experimental program. Thus far, 4 months later, not only have I not been enrolled—I have not even heard from the hospital, although I have called. And each time I check, it is the same story—well, there is some paperwork involved in setting this up; there are some administrative problems, there are some funding problems, there are some coordination problems. And meanwhile, each day goes by, and some of these coordination problems will be coordinated 20 or 30 years from now, and I will not be the beneficiary of any of that.

I guess this logjam of treatment is what I think is the basic problem. We are all concerned about research, and that is happening, but for many patients, for the 19,000 or 20,000 that have been diagnosed thus far, their concern is, What do I do for today and tomorrow, and how do I do it, and where do I go for help?

And the fact that we have this tremendous inertia that is apparently composed of perhaps legal components, there may be some technical and other reasons, but nevertheless, their effect is the same. At the end of the pipeline, nothing is coming through. And people like myself and Mrs. Kushnick can testify to that.

The **Chairman**. Thank you.

Mr. Levi, what kinds of educational efforts have really been proved most successful in reaching those at risk of obtaining AIDS—if you could help us there, we would appreciate it.

Mr. **Levi**. To a large extent, they have been community-based efforts that are speaking to the risk 44 group in their own language.

To be very frank, statements from health officials about not exchanging bodily fluids does not really get the message across. I mean, what do we mean by bodily fluids? We are talking about sexual practices that are very much a part of people's self-definition. And so we need to not only transmit information, but provide the counseling and the psychological support to teach them to integrate those guidelines into their lives.

And so, in some of the larger cities where there have been significant gay community efforts in that regard, there have been across-the-board efforts not only to transmit the basic intormation, but to provide support groups, and to change the consensus within the community as to what is acceptable behavior and what is not. And that is what has been effective, and that involves probably a level of explicitness and a level of discussion of, in the case of gay groups, homosexuality, that a lot of Government officials are not comfortable with.

But if we are going to treat this as a public health issue, we cannot avoid that directness, because otherwise we are going to see the virus continue to be transmitted.

The CHAIRMAN. What additional information has proven successful or even useful for families and friends of AIDS victims? Is there anything you can help us with there?

Mr. LEVI. Unfortunately, people do not start to pay attention to this issue until it directly affects them. I am not sure that we have come up with—we all talk about how we need more education, and how we need to overcome public fears. I am not sure we have got a handle on what exactly will work, precisely.

But one thing that I think is really important is to have some effective and powerful leadership from the very top. You know, this is the Nation's No. 1 health priority, and yet President Reagan has only discussed the subject twice. And I think that some real leadership from the White House in helping people to get compassion for those who have the disease, and to inspire people to overcome their fears and to deal with this as the national public health problem that it is, I think that would be a tremendous help.

The CHAIRMAN. Thank you.

Mrs. Kushnick, what advice do you have for parents who continue to be afraid of the casual transmission of AIDS?

Mrs. KUSHNICK. I think that part of the problem we have is that we have not worked with the Parent-Teachers Association. When I was at CDC sitting on that symposium, the president of the National PTA was there, a very responsible woman. Most people do not want to live their lives in fear, and I do not think that people really want to pull their children out of school. I think what happens is that a momentum builds up, and everybody makes everyone crazy, or as Shirley Fanan said, "The community goes berserk," and one person feeds off the next.

I think what has to happen—I found in my own instances, when I went through Sara entering kindergarten in September, when I found out the names of the people who were having a problem, I called them, and I sat down and talked to them, and I explained to them what was known about AIDS, what was known about the transmission of AIDS, explaining how healthy Sara had been, et cetera, et cetera—and those people were fine; then they had no problem. But it was simply talking to them.

You cannot talk "at" people; you have to talk "to" them, and we are really not doing that effectively. We need to do that. We are 2 years behind. I mean, even sitting at CDC in June 1985, writing guidelines for children in school seems too insane to me, because this should have been done in 1983 and 1984. We always seem to be a year, a year and a half behind what should be going on, and I think it is very, very important to work with the parent-teacher organizations.

The CHAIRMAN. Now, you have been involved in the past with the Centers for Disease Control in setting these guidelines for AIDS.

Mrs. KUSHNICK. Yes.

The CHAIRMAN. Could you give us your views as a lay member as to how effective such a committee was, and give us a little understanding of the process and outline for us the guideline formulation process.

Mrs. KUSHNICK. Well, I have a different opinion of Centers for Disease Control than Mr. Smith does. I believe early on in the crisis, in 1981—and we keep saying 1981, but the virus has been in the country since the midseventies—1981 was when the first five cases were formally written up. I think that the National Hemophiliac Association was a very powerful body, and they went in and got the CDC's attention. And that is, I think, why Mr. Smith feels that their relationship with CDC was very good. They were talking to the National Hemophiliac Foundation.

They were not talking to the gay groups, and they certainly were not dealing effectively with the Haitian population. I mean, you cannot send a person who looks like an FBI agent in to talk to a Haitian about his sex life; it just does not work. And that was what was going on early on.

What has happened now is they are overwhelmed. When Martha Rogers became the pediatric epidemiologist at CDC, things started to change a bit. The man who was there before her was basically ineffectual. He was moved to NIH. [Laughter.]

I did not realize that was that funny.

But Martha has done an incredible job. I get a lot of calls from parents around the country who have children with AIDS with blood transfusions, or have just been tested positive for HTLV-III. One was just about 6 weeks ago, twins born in January 1985. One of the babies has AIDS, or is positive for HTLV-III. And I called Martha, and I say, "Have you heard about this case yet?" And she says, "No, I have not heard about this case." And I say, "Write this one down."

There were pediatric cases where kids with AIDS—related complex were not even being counted. And I said to Martha, "Are you counting these kids?" and she said, "We do not even have the staff to count the AIDS cases. Forget about counting the ARC cases."

I think CDC gets involved in a lot of politics, and I think the politics between CDC and FDA, and then Washington, somewhere in all of that there is too much politics involved for me as a layperson in medicine.

One thing CDC could do—and of course, you would have to fund it—is—do you know what the Morbidity and Mortality Weekly Report is—is that familiar to anybody?

The CHAIRMAN. Yes; we are familiar with it.

Mrs. KUSHNICK. All right. the MMWR used to be in the late seventies dispensed free to all physicians around the country. Well, in 1980, with the budget cutbacks, they stopped distributing the MMWR to physicians free. Now, most physicians, of course, do not make enough money to spend $125 a year subscribing to this, so they do not. And what happened early on is that the information is not getting out to the practicing physicians. And that is the problem with CDC. The CDC does not effectively communicate with the Public Health Service agencies on a local level, on a community, county, State basis, to then inform the practicing physicians and the hospital. That, to me, is what is missing in all of this, and that would help a great deal with education.

Senator KENNEDY. Would the Chairman yield for just a second?

The CHAIRMAN. Yes.

Senator KENNEDY. We are going to have a vote at 11 o'clock, and I would like to submit my questions. I have to go to the floor now.

If I could just thank this panel. I think, as one who has been the former chairman of the Health Committee, I think it is extremely difficult to come and share these health needs, talking about children or individuals or loved ones. But your comments and testimony and insight into this whole issue have been enormously helpful and valuable. I have been fascinated by your responses to the questions and by your testimony itself.

I have some legislation that tries to deal with some of the community-based activities that we have talked about. Obviously, it is only a small element in our Federal response, and I would appreciate it if you might get a chance to look at it.

But I wanted to indicate to you before leaving how much I personally appreciate your presence here. It is enormously moving testimony, and I think you made the case extraordinarily effectively. I look forward to working with you in the future.

I thank the Chair.

Mrs. KUSHNICK. Thank you, Senator.

The CHAIRMAN. Thank you, Senator Kennedy.

I appreciate Senator Kennedy and my other colleagues' being here. I do not know anybody who has worked harder on public health problems than Senator Kennedy unless it is, of course, I, myself! I want to personally compliment him and the other Members here, who have worked very hard on these problems.

We hope we can come up with some resolution to some of these problems.

Just one last question. What do you think should be the respective role of the Government at the Federal, State and local levels in financing and conducting AIDS-related patient care research, public education, screening, surveillance, et cetera? Would you could give us the benefit of your opinions on that?

Mrs. KUSHNICK. Do you want me to do that, Senator?

The CHAIRMAN. Yes.

Mrs. KUSHNICK. I think that it is important for the Government to work with the National AIDS Network and the American Foundation for AIDS Research. I think that using expertise of laypeople will assist the Federal Government in formulating options for people that will be moved quickly into the community.

What starts to happen is that everybody stops talking to everybody else, or everybody comes from their own political base, and then it becomes very difficult. People stop communicating, they get polarized.

I think that if we could form an independent lay committee to work with the Government, an oversight committee made up of people who are out there in the community, not politically based people, to just assist the Federal Government, I think things would happen a lot faster.

Again, as I said before, I just think the whole circle of government—and this is, as you can see from around the room, a very media-conscious disease at the moment. I mean, the press pays attention to it. And part of the problem we are really having to me is the press, because they tend to want to do what is sensational, because if it is slightly sensational, they will get a rating. So the 10-second spot may be a little more sensational than the story actually is; but people do not tune in to hear the story. They hear the 10-second spot. And I think that is something that needs to be addressed, also.

And I would like to see the Government really use the media effectively. I would love to see someone from this committee on national television talking to the American public—I think that would be enormously helpful—or the Assistant Secretary for Public Health, or the Public Health Director, or the Surgeon General—someone with accurate information, because that is really what is happening. We are not getting proper information, because most of the physicians are not educated in dealing with the general population.

The CHAIRMAN. Thank you.

Let me turn to Senator Metzenbaum.

Senator MEZENBAUM. I just have one question. If it were in your power to have one thing done, Mr. Smith, Mrs. Kushnick, and Mr. Levi, what would that one thing be? What would you ask Government to do? I do want to commend all of you. I think your testimony has been as impressive as any that I have ever heard before any Senate committee, and your ability to relate on a personal basis has been, I think, just absolutely magnificent.

I am only sorry that more of our colleagues are not here to have the opportunity and privilege of hearing you.

Mr. Smith.

Mr. SMITH. The difficult question you ask could be categorized in the various ways of how you judge importance. And I suppose from my point of view, I ought to be judging it on a very personal level.

But I suspicion that overall in our society, what we really have to solve with the AIDS issue is the fear that is promoted. And that can only be promoted through some topflight, continuing, depth-type, educational, transmission of information. I do not know any way around the fear problem. Ultimately, everybody has to live with that, because we all have some fears of unknowns. The ultimate fear we all have is that we will die, and how we deal with that is everybody's challenge.

So if you can live without fear, you can enjoy life. But if you are fearing, and if you are apprehensive, then all those days' experiences turn out to be somewhat diminished.

So I would say that the government's role has got to be to educate,to disseminate, to provide a rationale for living without fear, with AIDS.

Senator **METZENBAUM**. Thank you.

Mrs. Kushnick.

Mrs. **KUSHNICK**. I think what I would do is I would help Elizabeth Kubler-Ross get some funding for a home for children with AIDS who are abandoned in hospitals. And, as Mr. Levi said, most of these children are abandoned in hospitals, and they are living in acute care situations where there really is not a need for that, but there is no place to send them because this country does not have a facility available to them.

It is sort of a double-edged sword for me. I have a problem dealing with isolating these children, but I also know that there is noplace for any children that are sick to go. I think that is probably one of the things I would like to see happen.

She has had a lot of trouble because the farm that she had in Virginia picked out to house these children, the neighbors got real upset and said they did not want the children in the neighborhood, so they have been tied up in litigation for the last year. That is what I would like to see happen.

And one more thing, if I could. I would like Nancy Reagan to invite some of these children to the White House for an Easter egg hunt next year, or something.

Senator **METZENBAUM**. How many children? I am just shocked by the knowledge that there are children who are abandoned by their parents. How many would you say there are?

Mrs. **KUSHNICK**. Again, I am dealing with CDC statistics, which are not accurate. When my son died, pediatric AIDS was not even counted. There was no such thing as pediatric AIDS—which was the reason my husband and I decided to go public with this story. I would have felt like an accessory to murder if I had not.

In November 1984, they started finally counting the cases, and they counted 72 pediatric cases. As of January 30, 1986, there were 231 pediatric AIDS cases, which means they tripled in 15 months, or more than tripled in less than 15 months.

Pediatric AIDS is going to be a growing, growing problem.

Senator **METZENBAUM**. Yes, but you are certainly not suggesting that all of the pediatric AIDS cases are abandoned children, are you?

Mrs. **KUSHNICK**. Well, 80 percent of them, probably, Senator, because——

Senator **METZENBAUM**. Eighty percent?

Mrs. **KUSHNICK** [continuing]. About 80 percent of the children, they are estimating are children who are born with AIDS, I.V. drug-user parents, or a person with AIDS who gives birth to a child who cannot care for that child, so those kids are being abandoned in hospitals.

United College Medical Center in Newark, New Jersey has really been dealing with the primary patient population. Even the private care facilities—I mean, even children who are living with their parents are suffering. The problem that they are having is they do not know how long these children will live. There is a different treatment for them than an adult AIDS case. And they are treating them with intravenous gamma-immune, which seems to be keeping them alive. So they do not know how long these children are going to live.

Senator METZENBAUM. But you have not answered my question. I understand you do not have an exact count, but would say there are 10, or 50, or 100?

Mrs. KUSHNICK. Oh, no, they are in the hundreds.

Senator METZENBAUM. That are abandoned children?

Mrs. KUSHNICK. Yes, that are living in hospitals. If you want, just call Deborah Rizzi, at United Hospital Medical Center, Newark, New Jersey, Dr. Oleske's group. She can give you an exact number of how many children they are treating there. Arge Rubenstein has another—I think he has got 70 or 80 children in New York.

Senator METZENBAUM. But aren't some of these children who are in the hospital, their parents are coming to see them and be with them, as distinguished from being abandoned?

Mrs. KUSHNICK. No. Most of them are abandoned, Senator. I know that is hard to believe, but it is true.

Senator METZENBAUM. That is amazing.

Mr. Levi.

Mr. LEVI. As a politician, Senator, you should never ask a person to choose just one thing. I think if you are asking for a sort of a new initiative that the Federal Government should engage in, then I would——

Senator METZENBAUM. No. I am just saying whether new, old, whatever.

Mr. LEVI. I think at this point the most important thing the Federal Government can do is take steps to assure comprehensive care and counseling for all people with AIDS or HTLV-III infection. That is probably the most important thing we can do to mitigate the human suffering involved and also, because counseling would be part of it, help prevent the further transmission and spread of the disease, if we provided comprehensive, compassionate care and counseling for everyone who has HTLV-III infection.

Senator METZENBAUM. I appreciate your answers, and I do not mean in my response to be critical. But it is interesting that none of you have mentioned the need to have a breakthrough, more funding, more efforts, more push with respect to research and finding an answer. And I understand that that probably is implicit in what you are thinking and saying. You are talking about the immediacy of the problem.

Mr. LEVI. I think that what we are saying probably reflects one of problems that we, as people who are in contact with people who are dying all the time, have with the focus on developing a vaccine and the ultimate cure.

All those things, as I think the scientists will tell you on the next panel, are years off in the future, and we have a major public health problem to cope with right now. And those are the services, and those are the prevention mechanisms that have to be put in place until that wonderful breakthrough happens.

Senator METZENBAUM. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Simon.

Senator SIMON. Thank you, Mr. Chairman.

First, I want to agree with Senator Metzenbaum. I cannot remember having three witnesses who have impressed me more, and I commend you.

Mrs. Kushnick made a suggestion that I want to follow up on—I address this question to my colleagues here on the Committee with me—that the Administration form a Presidential Commission.

I wonder if the members of this committee could not send a letter to the President, requesting that he appoint such a commission. We are not talking about creating any new entity.

The CHAIRMAN. We have already sent that message to staff. I liked your idea of taking care of abandoned children with AIDS and AIDS public education. We must remember that we are spending a massive amount of money on trying to resolve the problem of AIDS. We still have the problem of Gramm-Rudman, and the sequestration orders. We'll have to look over the whole public health budget and see what we can do to make sure adequate funds are available in those areas.

Senator SIMON. If I may be more specific, I think if the members of this committee——

The CHAIRMAN. I think we can do that.

Senator SIMON. Let us do that. I think that is an excellent, very practical suggestion.

Mrs. KUSHNICK. I think it would help enormously.

Senator SIMON. OK. We will follow through on that, Mrs. Kushnick. That is a tribute to you and to that little boy who died.

Mrs. KUSHNICK. Thank you.

Mr. LEVI. Senator, if I could just add one thing, I think one of the reasons that we talk about sharing information is that there is an incredible amount of expertise out there. And the gay community and AIDS service groups have been dealing with these problems for 5 years now. And a lot of what we are talking about is having the Federal Government step in and play a role so that other communities do not reinvent the wheel, so there can be an information transfer.

As you will hear from the third panel, we know how to cut the costs of care for persons with AIDS. We just need to teach other communities around the country how to do that. And it turns out that is the more compassionate way of caring for people. So that is, whether it is in the form of a commission or some other mechanism that the Government employs, what we are really talking about is not even a high-budget item. We are talking about sharing information and sharing expertise.

Senator SIMON. Well, this is why I like Mrs. Kushnick's suggestion. It elevates the issue, it gives it some public attention, some practical public attention. For example, these abandoned children, maybe I am the only member of the committee who did not realize this problem. I think there are things out there that we can do more on.

Mr. Smith, you told your personal story, and I commend you for doing it. You are man with a wife and 6 children. You mentioned that you hear information about things that are available, and yet they are not coming to Nathan Smith. What is the blockage there, and where are you going to get help?

Mr. SMITH. Well, of course, on a continuing basis, I have identified a local doctor, and he is in consultation with the doctors who diagnosed and treated me when I was hospitalized in Houston.

But when I was there in Houston, they were talking about experimental drugs, three different ones that they were going to try, Ribavirin and two others. And as part of their experimental protocol, all of their AIDS patients would have been enrolled in that program.

I do not know the full story, but I am understanding that their funding for this, which was coming through some Federal sources, had been involved in essentially a territorial struggle between certain of the research elements of the Federal Government, and that was the difficulty they were having.

Now, I do not know the full story behind it. But all I know is that, despite whatever pressures that I would like to be able to bring to bear on the situation, it is 4 months after release from the hospital, and I am not involved in an experimental program. I am taking antibiotics twice a day, and that is as far as it goes.

The frustration is that I know that a whole hospital has been designated in the Houston area for the treatment of AIDS, and that designation is presumably being expedited. But I also know that it has not happened to me. And I do not know where the roadblock occurs. Apparently, they have the drugs; apparently, they have the capacity to provide the treatment. But it is not getting to the patients. And if that is a problem that can be remedied through changing governmental regulations, through overseeing this with another type of agency that can coordinate all of what is going on, I am not sure.

I really do not know the answer; all I know is the problem.

Senator SIMON. OK. Let me say to anybody here who is with NIH or HHS, I want to follow through specifically with Mr. Smith, not because of you alone, but I want to find out what is happening here. And I am going to be back in touch with you to see what is happening and see if we cannot move on this.

Mrs. KUSHNICK. Senator, if I may, unfortunately, Mr. Smith is not the exception. This is the rule. This is going on around the country.

Senator SIMON. I assumed that, yes.

Mrs. KUSHNICK. And I think it is hung up somewhere between NIH and FDA. And again, I think what happens is that the doctors are very quick to go to the media and announce things that are not really there. And then they get people's hopes up because it gets filtered down, and then we find out that this is not there anyway. The Compound "S" situation on the CBS evening news was horrendous. I mean, there are going to be 250 people now in this drug trial; and half of them, it is going to be a placebo trial. So we are talking about thousands of people who are suffering from AIDS who want this medication because they heard about it on the CBS evening news, and NIH is only planning on giving it to 125 people.

Senator SIMON. Mr. Smith, I do not mean to focus everything just on you, but I think you symbolize something. From your view-point, if the FDA says, "Well, there is too much of a risk at this point for you to be receiving some of these treatments," you are still willing to take some risk; is that correct?

Mr. SMITH. Right. I do not believe that there is any progress being made until you accept a certain amount of risk. I was taking blood products throughout my entire life and accepting the known risks of hepatitis exposure and other kinds of viral contaminants, but I had to have the treatment in order to function, in order to raise a family, pay taxes, and maintain a job. Now, that future is a little dimmer because of AIDS, and if I am going to have a future, it has to come on the basis of another assumption of risk.

Now, I do not know the legal issues. Maybe people say you can never assume a mortal risk. But I am willing, if I could find a way, and the question is how can we provide the way.

Senator SIMON. Fine.

Well, I thank the three of you very, very much.

Thank you, Mr. Chairman.

The CHAIRMAN. I think this has been terrific testimony, and I want to thank all three of you. Your testimonies presage well the remaining hearings and we are very grateful to you.

Thank you for being here.

Because of time constraints, I will have to ask the remaining witnesses to limit their oral testimonies to 5 minutes each. We will be happy to print the full written text of each statement in the record.

Without objection, we will place a statement of Senator Claiborne Pell in the record at the beginning of this hearing.

The CHAIRMAN. The next two panels of witnesses are from the administration.

We are pleased to have testimony from two key representatives of the administration responsible for the formulation and implementation of AIDS policy.

At the table, we now to have Dr. Donald Ian MacDonald, who is Acting Assistant Secretary for Health and in that position oversees the AIDS efforts of the Public Health Service.

Seated beside Dr. MacDonald is Dr. Walter Dowdle, Acting AIDS Coordinator, Public Health Service; and accompanying Drs. MacDonald and Dowdle are members of the Public Health Service Executive Task Force on AIDS which Dr. Dowdle chairs; Dr. Henry Meyer, of the Food and Drug Administration; Dr. Anthony Fauci, National Institutes of Health; Dr. Donald Hopkins, of the Centers for Disease Control; Dr. Frederick Goodwin, of the Alcohol, Drug Abuse and Mental Health Administration; Dr. Audrey Manley, of the Health Resources and Services Administration, and Ms. Shellie Lengel, of the Office of Public Affairs, Public Health Service.

We are happy to welcome all of you to the committee today. We are very proud of the work you do.

We are in the middle of a live quorum on the Floor and I may have to leave at any minute. I think what we will do is begin the testimony of Dr. MacDonald. If you can, please limit it to 5 minutes allowing us time for questions.

I do not know how many Senators will be here, but I have a number of questions I would like to ask.

So, Dr. MacDonald, we will begin with you.

STATEMENT OF DR. DONALD IAN MacDONALD, ACTING ASSISTANT SECRETARY FOR HEALTH, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. WALTER DOWDLE, ACTING AIDS COORDINATOR, PHS; DR. HENRY MEYER, FOOD AND DRUG ADMINISTRATION; DR. ANTHONY FAUCI, NATIONAL INSTITUTES OF HEALTH; DR. DONALD HOPKINS, CENTERS FOR DISEASE CONTROL; DR. FREDERICK GOODWIN, ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION; DR. AUDREY MANLEY, HEALTH RESOURCES AND SERVICES ADMINISTRATION, AND SHELLIE LENGEL, OFFICE OF PUBLIC AFFAIRS, PHS

Dr. MacDonald. Mr. Chairman, members of tbe committee, we are pleased to be here, and we will try to rush through our testimony.

The format that I would like to use, if I could show you that first chart, is to give you an idea of how we are coordinating and pulling together the AIDS effort in the Public Health Service.

The Public Health Service early on recognized the tremendous importance of AIDS, and the Assistant Secretary for Health, Dr. Edward Brandt, appointed several years ago an Executive Task Force made up of members of the agencies of the Public Health Service. That group has met on a regular basis every 2 weeks for the last several years, and deals with a variety of cross-cutting issues of policy, sharing of progress and plans.

The group is made up of committee chairmen who chair subgroups dealing with more specific areas of AIDS concerns and other Public Health staff. In going around the chart there, I might start with CDC, represented today by Dr. Hopkins, on my left.

It was the CDC, best known as detectives and teachers and preventers, who first became involved with AIDS in 1981, as they became aware of new disease conditions, one in fact developing an unusual form of cancer, and the other, an opportunistic infection. The CDC continues to monitor the epidemiology and natural history of the disease. They have been mentioned this morning in regard to monitoring the numbers of people with AIDS and the number of deaths.

The CDC was also able to help us, before we knew whether this was a viral illness, to identify high-risk groups and to propose strategies to deal with AIDS. In dealing with those modes of transmission, it was helpful to understand not only who the high-risk groups were, but largely through the results of that same epidemiologic effort, we came to an understanding that this is not a casually-transmitted disease. This information has been tremendously reassuring to many. The CDC has been responsible for pulling together a series of guidelines, some of which have already been mentioned.

In 1985, September-October, we published the Public Health Service Action Plan, which has three main components. One was to continue and clarify the epidemiology and natural history of the disease. The second was to deal with public education—and it has been said by some that the vaccine we have today is information—and to use that information to encourage responsible measures to prevent infection in those who are uninfected, and to help others who are infected to keep from infecting others. The third major part of our plan, and that has been well-mentioned also, is to look for treatment and vaccine in our research establishments.

The second member of the task force represents the Food and Drug Administration, Dr. Harry Meyer, sitting to my right. The FDA has been very active in a number of areas. One was in learning who the high-risk blood donors were likely to be; efforts have been taken to safeguard the blood supply by exclusion of donors less likely to be infected.

In March 1985, with the release of the ELISA antibody test, there was a scientific breakthrough to make our blood supply safer. And in the area of blood products, such as the Factor-8 mentioned by Mr. Smith, there are chemical and heat treatment of those products to make them safer.

ADAMHA is represented here by Dr. Fred Goodwin, immediately to my left. Their responsibilities have been not just in dealing with the psychological aspects of AIDS in relation to fear and the importance of behavior change, but in the understanding that a major part of this problem lies within the drug use community. Over 25 percent of all people with AIDS are IV drug users, and it is in that population that we worry most about heterosexual spread. As was mentioned earlier, the pediatric neonatal cases also come from that population. It is difficult to know how to reach the I V drug user, how to change their behavior. That is the work of the ADAMHA committee.

The third area that we understood fairly early on is that this virus the HTLV-III virus, attacks the immune system of humans, causing difficulty in dealing with certain cancers and infectious agents. We understood later that it affects also the brain, and in infecting the brain, causes changes in cognition and behavior and motor performance, which are terribly important.

I introduce also Shellie Lengel, third from my left, who heads the Assistant Secretary for Health's Public Affairs Office and is responsible for pulling together information and education activities. This includes a variety of efforts both in Government and with organizations, such as the Red Cross, outside of Government. She is working with the Surgeon General in preparation of his report to the public. Press conferences and a number of public affairs activities are within her committee's jurisdiction.

To her left is Dr. Audrey Manley, from the Health Resources and Services Administration. Her committee is concerned with patient care and health services delivery—things like hospice care and a number of issues that were mentioned which would fall under the domain of Dr. Manley's committee.

Last but certainly not least, Dr. Anthony Fauci, on my far right, who coordinates the NIH committee looking at vaccine development and therapeutic intervention. NIH has played a proud and important role in the discovery of the virus, in the development of drug testing, and now is hard at work on vaccines and antivirals.

Mrs. Kushnick in her comments related, one of the real problems that Dr. Fauci has, his wanting to deal with the reality that the science is not nearly where we would like it to be in terms of having a vaccine or antiviral agent on the street. But, I also want to point out the tremendous progress that has been made in what the scientists are beginning to call "soft optimism" about the future.

The three areas that the researchers work in are: Looking for a vaccine, as you have seen in the paper this week, there are a number of problems related to vaccines, but tremendous progress has already been made; the antiviral agents, those agents that will either kill or slow down the virus, are moving along rapidly and there is room for "soft optimism" there, also; and in the area of immune enhancers, progress is also being made.

To summarize this briefly, I would say that we have made tremendous progress, but we are well aware of the long distance we still need to go.

The CHAIRMAN. Thank you, Doctor.

[The prepared statement of Dr. MacDonald follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

STATEMENT OF

DONALD IAN MACDONALD, M.D.

ACTING ASSISTANT SECRETARY FOR HEALTH

PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

U.S. SENATE

APRIL 16, 1986

Mr. Chairman and Members of the Committee:

I am pleased to have this opportunity to discuss the Public Health Service's (PHS) efforts in combatting the epidemic of acquired immune deficiency syndrome (AIDS), our number one public health priority.

With me today at the table is Dr. Walter Dowdle, the Acting PHS AIDS Coordinator. Behind me are the AIDS coordinators for the various PHS agencies: Dr. Frederick Goodwin for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); Dr. Donald Hopkins for the Centers for Disease Control (CDC); Dr. Harry Meyer for the Food and Drug Administration (FDA); Dr. Anthony Fauci for the National Institutes of Health (NIH); Dr. Audrey Manley for the Health Resources and Services Administration (HRSA); and Ms. Shellie Lengel, Director of the PHS Office of Public Affairs.

The activities of the agencies are coordinated through the PHS Executive Task Force on AIDS (Chart 1). It is chaired by the PHS AIDS Coordinator and meets biweekly. Six workgroups of the Task Force meet at regular intervals to coordinate agency activities in specific areas:

- The Vaccine Development and Therapeutic Intervention workgroup is chaired by Dr. George Galasso, NIH;

- The Epidemiology and Prevention workgroup is chaired by Dr. Donald Hopkins, CDC;
- The Blood and Blood Products workgroup is chaired by Dr. Harry Meyer, FDA;
- The Psychological, Psychiatric, and Addiction Aspects workgroup is chaired by Dr. Frederick Goodwin, ADAMHA;
- The Information/Education workgroup is chaired by Ms. Shellie Lengel, OASH; and
- The Patient Care and Health Services Delivery workgroup is chaired by Dr. Audrey Manley, HRSA.

In addition to the PHS Executive Task Force, the agencies have their own task forces on AIDS which are chaired by the agency coordinators. An additional coordination point is my biweekly meeting with the agency heads. AIDS is a regular item on our agenda.

When I became Acting Assistant Secretary for Health, I recognized the need for a strong scientist-administrator to monitor closely all the AIDS projects under way throughout the

PHS. As our activity in this area has grown, the task of working closely with the agencies, looking for gaps in activities and making decisions that keep the PHS efforts on track has become more than a full time job. In December, I created the position of AIDS Coordinator and asked Dr. Dowdle to serve in this capacity.

In my remarks today, I will present an overview of our efforts organized within the context of the PHS Plan for the Prevention and Control of AIDS. This plan was developed by the PHS Executive Task Force on AIDS and published in outline form in the September/October 1985 issue of Public Health Reports. I would like to submit a copy for the record. The plan serves as a framework for our activities and those we coordinate with other Federal agencies, with State and local health departments, with professional organizations, and with volunteer groups. We used it as a guide for development of the 1987 AIDS budget, and anticipate using it in a similar way in future years.

Our goal is to eliminate transmission of HTLV-III/LAV infection by the year 2,000 with a decline in the incidence of AIDS thereafter. The PHS plan is based on the state of the art since the isolation of the AIDS virus and the development of the blood test to detect evidence of infection by the virus. In June, we will hold the first major review of this plan and will develop a consensus on the necessary modifications needed to respond to the changing demographics of AIDS through 1991.

Review of the AIDS Problem

The first cases of AIDS were recognized in 1981. Since that time, we have learned much about the pathogenesis and clinical manifestations of the disease. It is caused by the HTLV-III/LAV virus which attacks critical cells of the immune system causing a defect in a person's natural immunity. As a result, persons with AIDS are vulnerable to infections and cancers that would not be a threat to those whose immune systems were functioning normally. Patients are gradually weakened by these diseases and eventually die. The AIDS virus can also infect cells in the brain, causing a series of behavioral, cognitive, and motor disorders. This characteristic of the virus has important implications for therapy in that candidate drugs must be able to cross the blood-brain barrier.

AIDS has become a public health problem unprecedented in recent history. In the following charts, I would like to review for you the current extent of the problem: As of April 14, our most recent reporting date, there were 19,560 patients with AIDS reported to the Centers for Disease Control. The number of new cases of AIDS has increased each year since the disease was first identified (Chart 2). This trend will continue, although the rate of increase is slowing. We expect the number of AIDS cases to double over the next 13 to 14 months.

The major risk group patterns for infection have not changed markedly since the disease was first reported (Chart 3). More than 90 percent of the adult AIDS cases have occurred among homosexual or bisexual men and intravenous (IV) drug abusers. In addition to the 17 percent of heterosexual IV drug abusers, 11 percent of homosexual/bisexual men also report using IV drugs. Of the remaining 10 percent of cases, 0.9 percent are hemophiliacs, 1.4 percent are heterosexuals who have had sex either with an AIDS patient or with a person in a high risk group, and 1.9 percent have had a transfusion as their only probable source of infection. Approximately 2.1 percent of cases are people for whom a risk factor is not apparent, but who were born in another country where heterosexual transmission of infection appears to be more common than it is in the United States. Another 3.3 percent of cases have not had a probable means of infection identified either because of death, inability to follow-up or investigation still in progress.

On this map of the United States (Chart 4), are recorded by State, the number of cases reported to CDC as of April 14. As you can see every State has reported cases of AIDS. But five States--New York, California, Florida, New Jersey, and Texas--account for 75 percent of the total number of cases.

We know there are more persons infected with the AIDS virus than have become ill. Our estimate is about one million infected people in the United States. The incubation period can be long, ranging from 6 months to 6 years or more. Because experience with HTLV-III/LAV infection has been relatively brief, we can not be certain how many persons with antibody might acquire AIDS or show other signs of infection. Data from antibody positive populations that we have followed for the past 3 years show that 7 to 34 percent of these individuals go on to develop AIDS. However, we must assume that all persons with antibody are able to transmit the infection.

The AIDS virus is transmitted through sexual contact from an infected partner, through contaminated needles or syringes used by intravenous drug abusers, through contaminated blood and blood products, and from infected mothers to infants (Chart 5).

Working Assumptions for Planning

Our current plan is predicated on the assumption that, despite our best efforts, there will be neither an effective vaccine nor a means of preventing an infected person from developing AIDS before 1990. Therefore, our best means to control the spread of AIDS is to encourage people to take responsible measures to prevent becoming infected with the virus, or, if they carry the HTLV-III/LAV virus, to prevent infecting others. We know enough about the transmission of the virus to substantially curtail spread of it if current knowledge were applied. Because virus transmission results from a few personal behaviors, alteration of those behaviors is a powerful weapon for the control of AIDS.

Objectives for the Prevention and Control of AIDS

The objectives of the PHS plan fall into three broad areas (Chart 6):

I. Continue efforts to clarify the epidemiology and natural history of the disease;

II. Continue to implement a major public education effort, including health education/risk reduction techniques, to encourage behavioral changes; and

III. Expand research efforts to develop effective therapies and a vaccine.

I would like to focus my discussion by highlighting accomplishments over the past year and ongoing studies in these three areas.

I. EPIDEMIOLOGY AND NATURAL HISTORY

ADAMHA, CDC, and NIH support studies that attempt to further clarify the epidemiology and natural history of AIDS.

State health departments have reported AIDS cases to us since 1981. State data retrieved from the CDC standardized AIDS confidential case report form are important for showing current patterns of disease occurrence and for detecting newly emerging risk groups. It is from these surveillance data that we determine the demographics of AIDS and project trends.

In addition, epidemiologic studies on various groups of individuals provide information on who is at risk of getting the disease and how it is transmitted. Such studies have already given us much important information.

A key accomplishment during the last year was the completion of studies of family members of AIDS patients and health care workers that demonstrate the lack of casual transmission of AIDS. In studies of more than 300 household contacts, not one person--other than a sexual contact or child born to an infected mother--has become seropositive or developed AIDS as a result of living with AIDS patients. In studies of more than 1,400 health care workers, who have had close contact with AIDS patients, not one has developed AIDS or become seropositive as a result of contact with patients, other than through needle stick injuries. One unusual case of a mother, who became seropositive while caring for her infected infant, has been investigated by CDC. She failed to follow the usual precautions recommended for health care personnel in caring for her child. This case is not representative of what could be expected either in the households of most AIDS patients or in health care facilities.

We believe the results of our studies of families and health care workers allow us to say with confidence that AIDS is not spread by casual contact, such as sneezing, coughing or sharing meals with an AIDS patient. We have used the results of these studies to try to calm the public fear about contracting AIDS. The results have also allowed us to develop guidelines for schools, health care facilities, and other settings. I will discuss these guidelines and recommendations when I talk about our prevention/control programs.

Another study completed this year among Haitians living in New York City and Miami revealed heterosexual contact as a major mode of virus transmission in that population. This has important implications for future planning. We may not yet be seeing the full impact of heterosexual transmission in the U.S. Although not a frequently seen mode of transmission here, spread from men to women or women to men is common in central Africa and Haiti.

We continue to follow groups or cohorts of high risk individuals. NIH and CDC collaborate on a study of HTLV-III/LAV infection in Zaire, West Africa. The Zaire study will seek to define the natural history of infection in Africa and the risk associated with heterosexual transmission. Other efforts focus on studies of HTLV-III/LAV infection among female prostitutes in Africa and in the Caribbean.

The two largest of efforts are the NIH Multi-Center AIDS Cohort Study (MACS) and the CDC San Francisco Cohort Study. In the MACS study, which began in 1983, more than 5,000 homosexual males from four different geographical areas are participating. The San Francisco Cohort Study draws from a population of over 7,000 homosexual men who were originally enrolled in a hepatitis B study. This population is valuable because blood samples were collected and stored back to 1978, before the first cases of AIDS were reported. Both studies are powerful resources for determining which factors are associated with progression of infection, which behavioral practices place members of the high-risk group at especially high-risk of infection or illness, which factors are related to resistance and immunity, and finally, how the virus might change during the course of infection.

Recent evidence from ADAMHA investigators indicate that in the natural history of HTLV-III/LAV infection, pre-existing disturbances in central nervous system function (related to neuropsychiatric disorders and/or substance abuse) can compromise the immune system and may therefore comprise important risk factors for AIDS. ADAMHA supports research to clarify further the exact importance of these factors on the acquisition and progression of HTLV-III/LAV infection.

ADAMHA also has expanded studies of IV drug abusers. Of particular interest are the variant patterns of disease among IV drug abusers in different geographic regions of the United States and in different institutional settings, such as drug intake facilities, therapeutic communities, and prisons. Studies which focus on the epidemiology of AIDS among groups of prostitutes who do and do not use IV drugs are critical if we are to limit the spread of AIDS among the heterosexual population.

An important tool in these studies is the ELISA blood test, which detects people who are seropositive for antibodies to the HTLV-III/LAV. Studies have shown the ELISA test to be highly sensitive (ability of test to be positive for those infected) and specific (ability of test to be negative for those not infected). The first commercial ELISA test was approved for use in March 1985. Since that time, FDA has licensed several companies to market the test.

Blood banks and plasma centers in the United States began using the ELISA to screen blood and blood products as soon as it became available. This step, in combination with previous heat and chemical treatments that render clotting factors used to treat hemophilia free of virus, has added immensely to our ability to ensure the safety of our Nation's blood supply. In February 1986, FDA proposed regulations which would require the routine testing of all blood and plasma for antibody to HTLV-III/LAV. Effective as it is, the test cannot completely safeguard against the possibility of transmitting HTLV-III/LAV through blood and blood products. Our first line of defense is to request that those in the high risk groups not donate blood. To assure that these groups do not use blood collection facilities to obtain the test, we have worked with the States to make the ELISA test available at alternative test sites. We will continue to hear of new cases among people who received transfusions before the test was widely used. This is because of the long incubation period of the virus.

FDA is revising the labeling used on all antibody test kits to provide further instructions to laboratories about the appropriate use and interpretation of the HTLV-III/LAV antibody test. Evidence accumulated over the past year clearly suggests that the test can be used to assist in the confirmation of a diagnosis for AIDS or to identify high risk groups of people who are infecte The revised labeling will reflect the manner in which th test may appropriately be used for these broadened applications.

Meanwhile, research continues toward second generation assays that, for example, use recombinant DNA technology to produce viral antigens in bacteria or yeast systems. This methodology should produce assays with improved sensitivity and specificity and might eliminate the necessity of double checking results with laborious and expensive reference methods, such as the Western blot assay.

II. PREVENTION/CONTROL PROGRAMS

At present, the continuation and expansion of public education programs is our key approach to the prevention and control of AIDS. CDC and ADAMHA are doing health education/risk reduction work. Their projects are organized and carried out at the community level, with local people, who can target educational projects to the people in high risk groups. The PHS Public Affairs Office conducts a national information effort directed at all segments of the American public. The two efforts are closely related and coordinate with each other. All PHS information and education efforts carry the same messages to the public at large, both at the community and the national level. These messages tell people that to reduce your risk of acquiring AIDS:

o Don't have sex with multiple partners, or with persons who have had multiple partners (including prostitutes). The more partners you have, the greater your risk of contracting AIDS.

o Avoid sex with persons with AIDS, members of the risk groups, or persons who have had a positive result on the HTLV-III/LAV antibody test. If you do have sex with a person you think is infected, protect yourself by taking appropriate precautions.

  - Use condoms, which may reduce the possibility of transmitting and/or becoming infected with the virus.

  - Avoid practices that may injure body tissues (for example, anal intercourse).

- Avoid oral-genital contact.

- Avoid open-mouthed, intimate kissing.

o Don't use intravenous drugs; Don't share needles or syringes.

o If you believe that you may be at increased risk for HTLV-III/LAV infection, consult your physician for counseling. Consider asking to take the HTLV-III/LAV antibody test, which would enable you to know your status and take appropriate actions.

We have also developed more detailed recommendations for persons at increased risk of infection and for persons with positive results on the HTLV-III/LAV antibody test.

We recognize that AIDS is a community-wide problem with ramifications for other than just the high-risk groups. Through the fear and misinformation which has grown up around it, AIDS can adversely affect the well-being of citizens, regardless of whether or not they have any risk of infection.

For example, the American Association of Blood Banks reported a recent survey showing that 34 percent of Americans believe they can get AIDS by donating blood. Although this fear is groundless, it has caused a widespread inappropriate behavioral response. One way in which PHS is addressing fear and misinformation is through the PHS AIDS Hotline which presently receives upwards of 30,000 calls each month. The Hotline has been in operation since July 1983.

In addition, we have embarked in the past year, on a major mass media campaign in conjunction with the American Red Cross. Television and radio public service announcements have been developed and aired, and posters and pamphlets have been widely distributed. In an effort to help Americans understand AIDS, President Reagan has asked the Surgeon General to prepare a report. This report will be widely distributed to all segments of the public.

Other projects completed or under way include working with the American Medical Association to build up teams of physicians who can address community groups on AIDS and working with black and Hispanic groups to reach high risk minority individuals with AIDS information. These two minority groups bear a disproportionate share of the AIDS burden, comprising 25 and 14 percent of the group respectively. Most of the cases in these two minority groups are related to IV drug abuse.

A major effort throughout the PHS has been facilitating the flow of accurate information on AIDS to members of the press. Because AIDS receives extensive coverage, PHS staff spend many hours working with reporters. The PHS Office of Public Affairs also coordinates a continuing series of press briefings on AIDS. These efforts, we believe, have led to well-balanced, non-sensationalized coverage of the issue and we have been able to incorporate the PHS recommendations and prevention messages into many articles.

The first PHS messages focused on quelling the panic associated with AIDS. The next wave of messages, aimed at young people, will focus on the risks of experimenting with IV drugs and casual sex.

Since January, we have distributed nearly one million copies of our pamphlet, Facts About AIDS, through supermarkets in all parts of the country. We continue to use marketing techniques to make certain that our messages are understandable and acceptable. We continue to work with intermediary groups to increase the flow of information and to build networks of groups and individuals throughout the country. We continue to survey public knowledge about and attitudes towards AIDS and adjust our program accordingly.

AIDS Guidelines

Also as part of our education efforts, CDC has issued 11 sets of guidelines and recommendations on prevention of AIDS in the past 15 months.

These guidelines and recommendations are based upon surveillance data, epidemiologic investigations, laboratory studies, and the contributions of a large number of knowledgeable participants from the scientific and public health communities, selected organizations and institutions, and representatives of groups at increased risk. The guidelines delineate who is at increased risk of contracting and transmitting AIDS virus infection; provide a framework in which AIDS should be understood; and clarify how HTLV-III/LAV is transmitted.

The guidelines have had significant impact on many institutions in U.S. society. They have addressed problems faced by State and local health departments, those in the workplace, in clinical care settings, selected laboratories, schools, the blood banking system, and prisons.

As just one example of their usefulness, in a survey conducted by the Association of State and Territorial Health Officials, 38 of 45 States said they made recommendations or developed guidelines regarding school attendance. Most voluntarily commented that they used the guidelines CDC issued as a model.

A listing of the guidelines and recommendations published since January 1985 follows:

Guideline Title	Date of Distribution
Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome	January 11, 1985

World Health Organization Workshop: Conclusions and Recommendations on Acquired Immunodeficiency Syndrome	May 17,1985
Testing Donors of Organs, Tissue, and Semen for Antibody to HTLV-III/LAV	May 24, 1985
Education and Foster Care of Children with HTLV-III/LAV	August 30, 1985
Recommendations for Preventing Possible Transmission of HTLV-III/LAV from Tears	August 30, 1985
Update: Revised Public Health Service Definition of Persons Who Should Refrain from Donating Blood and Plasma-United States	September 6, 1985
Recommendations for Preventing Transmission of Infection with HTLV-III/LAV in the Workplace	November 15, 1985
Recommendations for Assisting in Prevention of Perinatal Transmission of HTLV-III/LAV and AIDS	December 6, 1985

Additional Recommendations to Reduce Sexual and Drug Abuse-Related Transmission of HTLV-III/LAV	March 14, 1986
AIDS in Correctional Facilities: A Report of the National Institute of Justice and American Correctional Association	March 28, 1986
Recommendations for Preventing Transmission of HTLV-III/LAV Infection during Invasive Procedures	April 11,1986

In the near future, we expect to publish recommendations addressing these additional topics:

- Recommendations on the use of HTLV-III/LAV antibody testing in dialysis centers;
- Optimal disinfection and sterilization strategies and recommendations for inactivation of HTLV-III/LAV

Health Education/Risk Reduction

The CDC and ADAMHA are pursuing a strategy of health education/risk reduction in selected populations. The goal of this strategy is to reduce transmission of the AIDS virus primarily by influencing the behavior of groups and individuals at highest risk of acquiring and spreading the virus. Because the effectiveness of these methods is not known, especially in modifying sexual or drug use behavior on such a large scale, assessment is a critical component of all our efforts.

Until now, most programs of AIDS health education/risk reduction have been conducted by community groups mainly serving the gay community. A number of such organizations have received some Federal, State, and/or local support, but the majority have operated with private contributions and volunteers. Setting precise objectives requires baseline data. Few communities now possess data on the extent to which various high-risk behaviors are being practiced by groups and individuals who must be reached with these messages.

Despite the need to strengthen the organization and focus of AIDS health education/risk reduction efforts, where these efforts are ongoing the results have been encouraging. And in certain localities, measurable change has occurred in behaviors that place individuals at risk of spreading or acquiring the virus.

Last year a study of randomly selected homosexual men in San Francisco found that 81 percent had reduced their risk of AIDS through monogamy, celibacy, or by otherwise avoiding "unsafe" practices. Moreover, other disease indices tend to affirm these findings: Sexually transmitted disease clinics in several major cities have reported that the incidence of rectal gonorrhea among homosexual men is down 70 to 85 percent.

In Fiscal Year 1986, we received funds to greatly expand our efforts in health education/risk reduction. The programs supported by these funds are designed to help implement the PHS strategy by assuring that:

o Every State with less than 100 AIDS cases is able to establish a basic health education/risk reduction program;

o Every State with 100 or more cases of AIDS and each major city with 1,000 or more cases is able to augment activities already under way; and

o Certain localities with well developed capabilities and community relationships can serve as demonstration areas of model AIDS health education/risk reduction efforts for the Nation.

One fundamental requirement of applicants for all three types of programs is the development of baseline prevalence data through which to establish specific measurable objectives that propose to affect various attitudes, knowledge, behaviors, and the level of HTLV-III/LAV infection at certain points in time.

Recently CDC entered into several cooperative agreements for examination of innovative approaches to AIDS health education/ risk reduction. Promising findings from these behavioral research efforts will be operationally tested in various demonstration areas.

Although hemophiliacs represent only a small proportion of the total AIDS cases, proportionately a higher percentage of them are infected than any other risk group. We are committed to working with the National Hemophilia Foundation and helping them to expand testing and counseling services to hemophiliacs and their families. In addition, CDC in collaboration with HRSA will be recommending that States maintain a close liaison with their local Comprehensive Hemophilia Treatment Centers. These Centers are a natural avenue to assure that members of this high-risk group and their dependents in each community receive needed health education/risk reduction information.

ADAMHA has targeted its messages to the high risk population of IV drug abusers. ADAMHA's efforts to limit the spread of AIDS have included the assessment of novel, ways to reach this population so that they will reduce behaviors that place them at risk of either acquiring the AIDS virus or transmitting it. ADAMHA is working with State drug abuse agencies to assist them in developing informational material and public health education on AIDS and drug abuse. Although the IV drug abusing population is particularly difficult to reach with health education messages, recent survey data from New York indicate that initial efforts have resulted in the reduction of needle sharing. In cooperation with local organizations, ADAMHA is beginning a targeted education effort towards prostitutes who use IV drugs. This effort will address our emerging concern with heterosexual transmission of AIDS.

Patient Care and Health Services Delivery

PHS provides health care for AIDS patients in populations for which we have direct responsibility--American Indians and Alaskan Natives. In addition, HRSA supports primary care health service in commmunity health centers, migrant health centers and maternal and child health centers. Several of these centers are in high risk areas, such as New York City, San Francisco, and Miami.

In anticipation of the availability of Federal funds, HRSA has prepared a draft plan for AIDS service demonstration projects in 4 major cities with the highest incidence of the disease. This plan will be closely coordinated with the new, $17.5 million Robert Wood Johnson Foundation program which supports the establishment of specialized comprehensive health and supportive service programs for people with AIDS and ARC.

III. RESEARCH ON EFFECTIVE THERAPIES AND VACCINES

The third approach laid out in the PHS plan is aimed at developing vaccines and effective therapies. NIH is the lead agency. FDA, ADAMHA and CDC also participate. Realizing this objective would give us the ultimate weapons against AIDS--a vaccine to prevent others from becoming infected and drugs to cure those who already have the virus.

The discovery that the etiologic agent of AIDS was a retrovirus was aided by basic cancer research. As a group, these viruses are characterized by the ability to integrate their genetic material into that of the host cell and remain dormant. Moreover, retroviruses can readily mutate. In addition, some retroviruses, such as the AIDS virus, can infect cells in the brain and avoid drugs that do not cross the blood brain barrier. These characteristics present a challenge to scientists who are developing therapies and vaccines.

Drug Development/Testing Activities

Within the past year, NIH established a drug development program for the systematic evaluation of antiviral agents--drugs that prevent virus replication--and substances that will reconstitute the immune system in patients with AIDS and AIDS-Related-Complex (ARC). Drug development at NIH is guided by an AIDS Drug Selection Committee which consists currently of 13 NIH scientists. Outside consultants will be added to the Committee this summer. The drug development program involves screening of agents for antiviral or immune modulation effect; preclinical testing; toxicology studies; and selection of candidate agents for use in clinical trials in man.

We are pursuing a number of approaches for identifying and testing active antiviral agents, including research studies, such as the one by ADAMHA scientists that recently identified HTLV-III/LAV receptor-specific peptide inhibitors. We also are working collaboratively with industry to include in the testing process agents that show promise in preclinical or clinical studies. The NIH has established a program with the United States Army Research Institute for Infectious Diseases to mass screen thousands of compounds per year. In addition, NIH intramural scientists have screened over 200 agents for activity in an assay which they developed.

NIH is currently supporting clinical studies on the a number of anti-retroviral agents. Industry also supports clinical studies on others. Two anti-retrovirals--AZT and Ribavirin--are now entering large scale multicenter studies involving patients with AIDS and ARC. Several other agents will be taken through preclinical testing this year.

NIH investigators are currently pursuing studies involving the use of drugs that might reconstitute the immune system of AIDS patients, such as interleukin 2, immune gamma interferon, and alpha interferon. These drugs are being evaluated as single agents, but they may be used in combination with anti-retroviral therapy in future studies. Other studies involve testing of drugs for the treatment of the opportunistic infections that plague AIDS patients.

This year NIH expects to fund ten AIDS treatment evaluation units at medical centers across the country to test the most promising agents arising from the preclinical development effort. These units will be geographically dispersed giving many more AIDS patients access to experimental therapies. Drugs will be selected for study in these units by the Drug Selection Committee.

FDA is responsible for assuring safe testing of experimental drugs, including those that may be of benefit in the treatment of AIDS. This is an issue of tremendous importance. We are all painfully aware of the desperate efforts of patients with this devastating disease to seek treatment. FDA and NIH are working closely to facilitate the development and evaluation of any therapeutic agent which appears to be promising.

For the record, I believe it is important to describe the process by which human drug testing begins (Chart 7). In order for clinical testing to proceed with products intended for use in the treatment of AIDS (or any other condition), an Investigational New Drug (IND) application is filed with FDA. The IND must contain information needed to demonstrate the anticipated safety of proceeding to test the drug in human subjects, including drug composition, manufacturing and control data, results of animal testing, training and experience of investigators and a plan for clinical investigation. In addition, assurance of informed consent and protection of the rights and safety of human subjects is required.

The initial clinical use of investigational drugs (Phase I) is intended to carefully assess the safety of the drug and to determine any pharmacologic effects that can be monitored. The number of patients entered into these pilot trials is necessarily limited until the initial assessment of toxicity is determined. As data are accumulated, studies are gradually expanded in scope and size to obtain safety and efficacy data to support marketing of the drug (Phases II and III).

The FDA has expedited the handling of all requests related to AIDS. The FDA has met on one or more occasions with every manufacturer who has expressed an interest in submitting an IND for the use of therapeutic products in AIDS or ARC or an AIDS vaccine to discuss the procedures for filing an IND.

In several instances, promising treatments relevant to AIDS have gained orphan drug status. This designation provides manufacturers with tax incentives, protocol assistance and some research funds to develop products for diseases that do not affect a large number of individuals (under 200,000) or products that are not expected to have sufficient sales to recover the company's research and development costs.

This is important in the development of drugs used to treat AIDS as well as drugs to treat the opportunistic infections associated with AIDS. Perhaps the best example of FDA's helping hand is with pentamidine, a drug which effectively treats the fatal form of pneumonia that often strikes AIDS patients. FDA and CDC scientists worked closely with the drug manufacturer to ensure the continued availability of this life-saving drug to patients in the United States, and the drug was approved in October 1984. More recently, the drugs HPA-23, AZT, and DHPG were also granted orphan drug status.

FDA has met with drug manufacturers and has assisted in the design of clinical plans so that studies on drugs which might prove to be useful therapeutic modalities for AIDS could be initiated rapidly once an IND is filed. This effort has enabled approval for a newly filed IND to be granted rapidly.

The FDA is in the process of gathering information for the public on current clinical studies utilizing drugs and biological products in the treatment of AIDS. Sponsors of INDs have been contacted and requested to allow this ordinarily confidential information to be made public. NIH has agreed to incorporate this information as it becomes available into their computerized data bank (Physician's Data Query). Our hope is that with the continued cooperation of the pharmaceutical industry, wide dissemination of this important information can be achieved.

Vaccine Development Activities

An immediate, concerted and targeted effort is under way concentrating directly on the preparation of a vaccine against HTLV-III/LAV. The only approach not being pursued is the use of inactivated whole virus vaccines because of the potential of viral nucleic acid to integrate into human cellular DNA and to turn on cellular transforming genes or recombine to generate new transforming viruses.

The first approach is using subunit components of the virus. Specific antigenic components are being purified and tested preclinically as vaccine candidates. A vaccine consisting of an isolated viral coat envelope protein has evoked an antibody response in Rhesus monkeys and challenge studies using live virus in vaccinated chimpanzees are being undertaken.

A second approach utilizes DNA recombinant techniques. Viral genomes that express specific antigenic glycoproteins are excised and inserted into bacterial or yeast vector systems which produce the antigen in large quantities. Antigens obtained in this fashion can serve both as vaccine candidates and for use in developing an improved assays for testing human sera for the presence of antibodies to the AIDS virus.

A third approach involves insertion into a vector virus, such as vaccinia, the HTLV-III/LAV genome segment which codes for the envelope protein. An advantage of vaccinia is that it was formerly used as a live virus vaccine against smallpox. The HTLV-III/LAV envelope antigen is produced as the vaccinia virus multiplies in the inoculated host. Vaccination with this recombinant virus thus serves as an efficient means of producing antibody against HTLV-III/LAV virus. It has already been demonstrated that mice injected with this recombinant vaccine will produce antibodies against the major envelope protein of HTLV-III/LAV.

The fourth approach is the chemical synthesis of a synthetic peptide that is identical to the outer coat of the human AIDS virus. Studies have shown that this peptide can elicit the formation of specific antibodies in rabbits against certain components of the AIDS virus, and that such antibodies were capable of inhibiting virus growth in culture. Recently, the synthetic peptide was also found to elicit an antibody response in chimpanzees. In late April, the chimpanzees will be inoculated with live AIDS virus to determine if the synthetic peptide will protect the animal from infection. If protection occurs, this finding will represent a significant advancement toward the development of an AIDS vaccine for use in humans.

The success of research that will lead to effective drugs, immune modulators, or other therapeutic approaches for AIDS will also depend greatly on the availability of well characterized animal models for this disease. This is particularly true for vaccine development, since demonstration of protection against infection in animals is an essential prerequisite to evaluation of a vaccine in man. The chimpanzee is presently the only animal which may be persistently infected with the AIDS virus and thus it is the ony animal that can be used for the final evaluation of potential vaccines. NIH is funding studies to find animal models lower on the evolutionary scale as possible substitutes for the chimpanzee.

Summary

In summary, the prevention and control of AIDS remains the number one health priority of the PHS. In the past year we have realigned our Executive Task Force on AIDS and appointed a full time PHS AIDS coordinator to monitor on a day-to-day basis the cross-cutting activities of the PHS agencies. We have a plan for the prevention and control of AIDS that focuses our efforts on public education to encourage people to change their behavior. I have outlined this plan for you and presented our activities in each of three areas.

This June, we will review that plan and develop a consensus on the necessary modifications needed to respond to the changing demographics of AIDS through 1991.

This completes my prepared statement, Mr. Chairman. My colleagues and I will be pleased to answer questions.

CHART 1

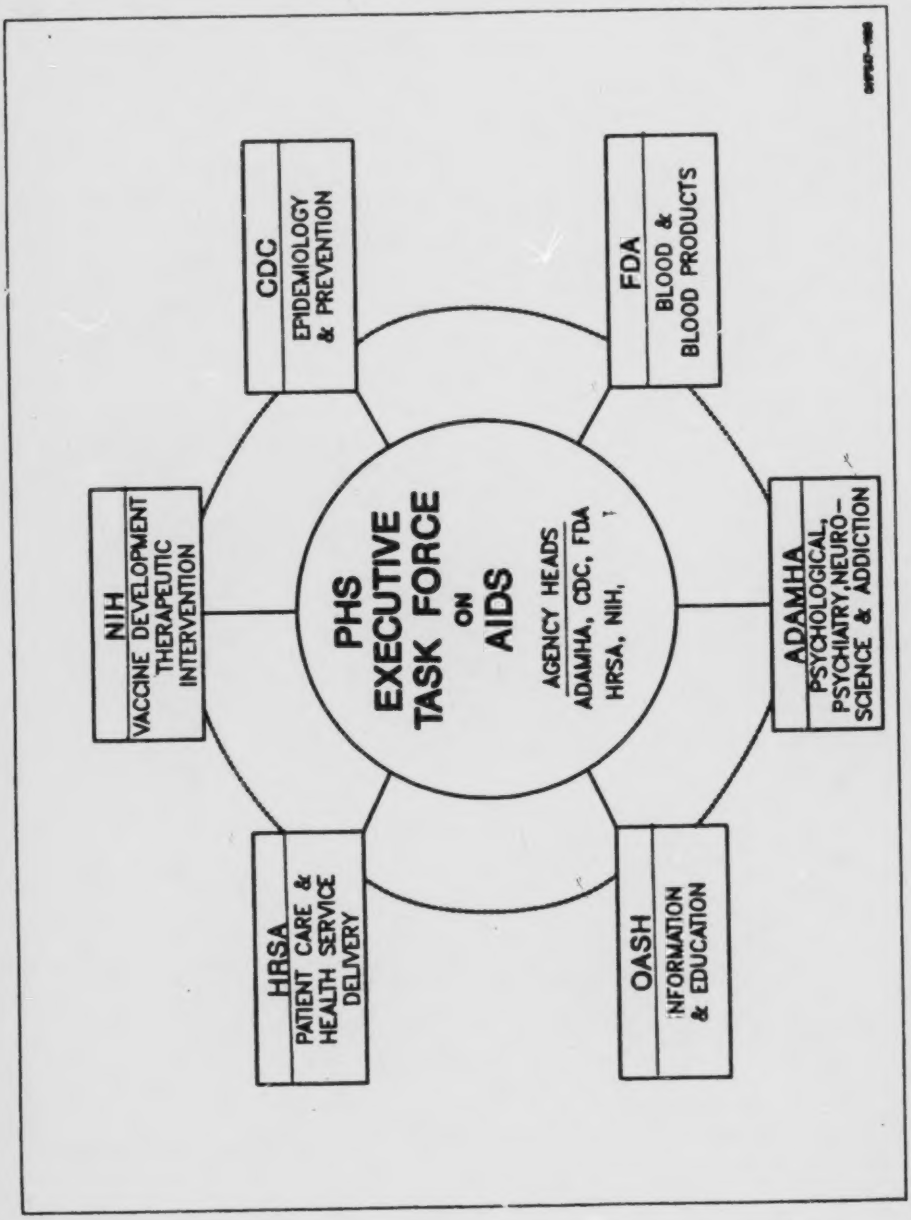
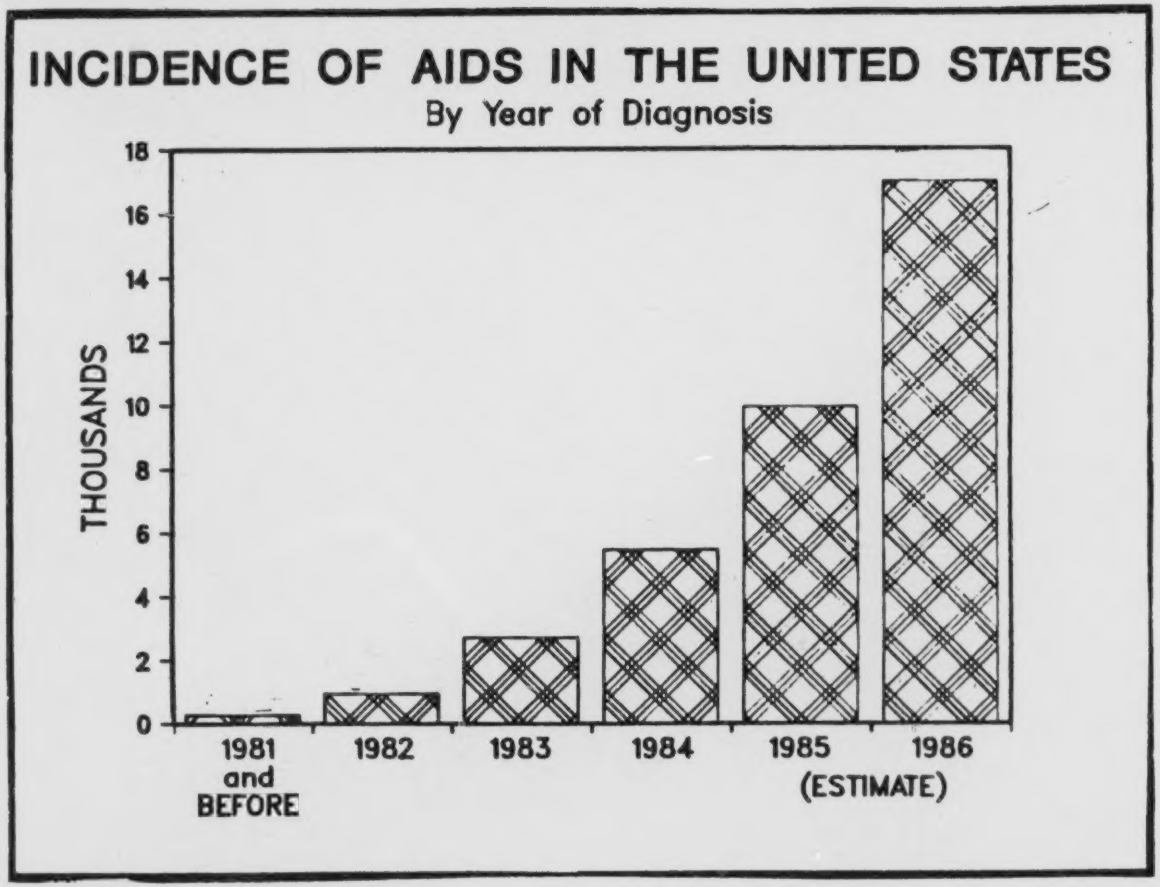

PHS
EXECUTIVE
TASK FORCE
ON
AIDS
AGENCY HEADS
ADAMHA, CDC, FDA
HRSA, NIH,
CDC
EPIDEMIOLOGY
& PREVENTION
FDA
BLOOD &
BLOOD PRODUCTS
NIH
VACCINE DEVELOPMENT
THERAPEUTIC
INTERVENTION
ADAMHA
PSYCHOLOGICAL,
PSYCHIATRY,NEURO-
SCIENCE & ADDICTION
HRSA
PATIENT CARE &
HEALTH SERVICE
DELIVERY
OASH
INFORMATION
& EDUCATION

CHART 2



INCIDENCE OF AIDS IN THE UNITED STATES

By Year of Diagnosis

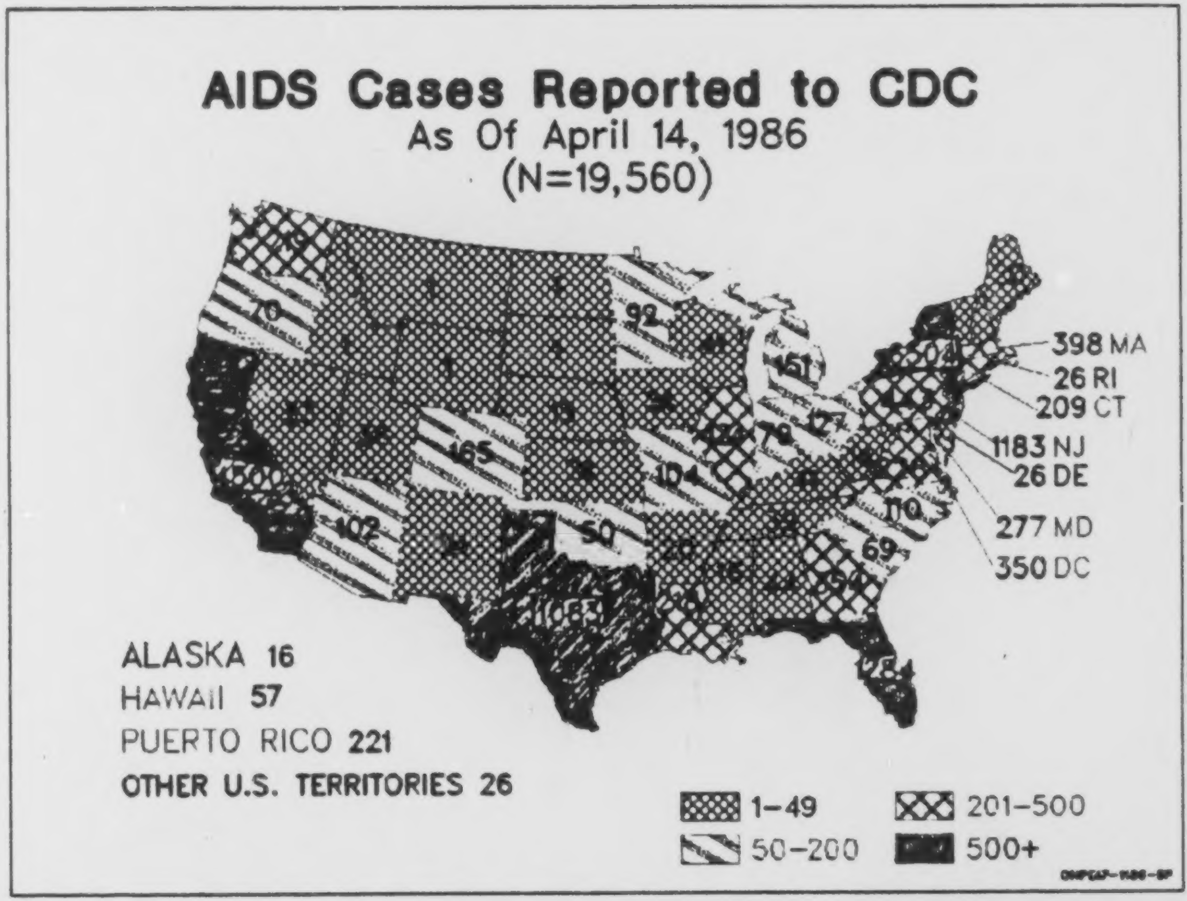
CHART 3

AIDS RISK GROUP PATTERNS
(PERCENTAGE OF NEW CASES)

	1982	1986
HOMOSEXUAL OR BISEXUAL MEN	70.8	73.6
INTRAVENOUS (IV) DRUG ABUSERS	16.8	16.8
PERSONS WITH HEMOPHILIA	0.8	0.9
HETEROSEXUAL PARTNERS OF HIGH RISK GROUPS	1.0	1.4
RECIPIENTS OF BLOOD OR BLOOD PRODUCTS	0.8	1.9
OTHER	9.8	5.4

[illegible]

CHART 4



AIDS Cases Reported to CDC
As Of April 14, 1986
(N=19,560)

70
92
151
165
104
79
127
110
50
102
69
398 MA
26 RI
209 CT
1183 NJ
26 DE
277 MD
350 DC
ALASKA 16
HAWAII 57
PUERTO RICO 221
OTHER U.S. TERRITORIES 26
1–49
50–200
201–500
500+

CHART 5

MODES OF TRANSMISSION

- SEXUAL
  - Homosexual
  - Heterosexual
- IV DRUG ABUSE
- PERINATAL
- BLOOD OR BLOOD PRODUCTS

CHART 5

PHS PREVENTION & CONTROL PLAN

- CLARIFY THE EPIDEMIOLOGY AND NATURAL HISTORY OF THE DISEASE
- IMPLEMENT PREVENTION/CONTROL PROGRAMS WITH CURRENT TECHNOLOGY
- DEVELOP EFFECTIVE THERAPIES AND A PREVENTIVE VACCINE

[illegible]

DRUG APPROVAL PROCESS

MARKETING

↑

NDA APPROVAL

↑

PHASE III
Expanded clinical trial
up to 1,000 patients

↑

PHASE II
Efficacy trial
100–200 patients

↑

PHASE I
Safety and dose tolerance
10–25 patients

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IND APPROVAL
FDA approval for studies in man

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PRECLINICAL TESTING
In vitro screening and animal toxicology

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DRUG DISCOVERY

The CHAIRMAN. Dr. MacDonald, I have a few questions for you and your panel, a number of whom I know quite well.

Do you have any plans to make experimental drugs available for trials on AIDS or AIDS-related complex patients, and if so, what are they?

Dr. MACDONALD. I will defer many of these questions to Dr. Dowdle or Dr. Fauci, but would like to say that we are moving well into clinical trials with a number of drugs. Five drugs are showing some degree of progress through the system, and by this summer we will have in fairly large clinical trial at least two of those agents.

Dr. Dowdle, or Dr. Fauci.

Dr. DOWDLE. It might be useful to talk about the process first.

Dr. Fauci, would you describe the process of making these available?

Dr. FAUCI. There are a number of agents that are in various stages of a process that will lead to their availability for treatment.

The first things that must be proven before a drug is made available widely are safety and efficacy. This is done in various phases. Phase 1 of a trial is to determine if the drug is safe to give; that we are not giving a drug which will do more harm to the patient than will the disease itself. Now, with a disease such as full-blown AIDS, which is a uniformly fatal disease, that still would hold true because, as I will discuss in a moment, there are some situations in which you can actually worsen the case.

Also, in phase 1 studies, you determine the optimum dosage and route of administration.

The next phase is phase 2, in which you determine the efficacy of the drug in small numbers of patients; in addition, this phase further confirms the safety.

Finally, there are phase 3 studies, in which efficacy is confirmed in a large number of patients and really nail down the efficacy and additional data is accumulated on the safety.

There are now a number of agents in phase 1 or early phase 2. They are being tested at a number of centers throughout the country. Testing at this point is being done in a limited number of patients because of concerns about the safety of the drugs.

Five drugs are being tested right now at different centers throughout the country: Suramin, azidothymidine that you heard about just a few minutes ago; Ribavirin, Foscarnet, and HPA-23.

This summer, the National Institute of Allergy and Infectious Diseases will establish a number of AIDS treatment evaluation units throughout the country. The proposals for these contract supported units have already been received, they have been reviewed, and we hope by early to midsummer to have at least 10 of these treatment evaluation units in operation. They will be geographically distributed throughout the country, and one or more of each of these agents will be available to patients at these various units. Approximately $20 million per year will be obligated to support those treatment evaluation units.

Hopefully, drugs that are now in limited testing will be tested on a much wider scale. One must have a situation in which there are patients available to do those kinds of studies. This is the reason why most of them will be located in areas where larger numbers of patients are available.

The CHAIRMAN. OK. There has been considerable newspaper publicity considering what appears to be a scientific dispute between American research efforts on AIDS and French research efforts. From these newspaper articles, it appears that at one time, there had been some collaboration between American research scientists and the French research community. Indeed, it would appear that both the American and the French may have been on their way to making significant contributions to the identification and culturing of either the same virus, or two viruses that are virtually identical coming from the same family.

I recognize that litigation could restrain some of the answers that you might want to give, but let me ask you some questions that I think would not affect current litigation.

The first one I have is cannot research be more effectively conducted by collaboration through recognized scientific experts than suffer by the current state of acrimony between the American and French research communities?

Dr. MACDONALD. Well, yes, I do want to be careful. But I think it is safe to say that there is tremendous international cooperation ongoing. What you see in the press and in reports of controversy is not diminishing the fact that on a regular basis, our scientists are traveling to France and other countries around the world, that we will be sending a large delegation of American scientists——.

The CHAIRMAN. So we are not stopping our efforts; we are making every effort to collaborate and to give help and cooperation wherever we can, nationally and internationally, including the private sector as well?

Dr. MACDONALD. Absolutely.

The CHAIRMAN. OK. I think that is the question I had there.

Recent research breakthroughs suggest that an AIDS vaccine may be feasible earlier than previously indicated and projected. Can you give us any indication as to any possible timeframe when you think such a vaccine might be available; how realistic are these expectations; what is the average time necessary to develop such a vaccine; is that changing with new technology; and when do you think these expectations might be fulfilled?

Dr. MACDONALD. I will pass that on to Dr. Fauci, but I would like to say first that this is another area, unrelated to the question asked by the previous panel, of not wanting to hold out a whole lot of hope, but on the other hand, to point out that we are making progress.

Dr. Fauci.

The CHAIRMAN. It seems to me you are getting a lot of the tough questions, Dr. Fauci.

Dr. MACDONALD. He is a good tough question answerer.

The CHAIRMAN. Yes, we know that. He is a good man.

Dr. FAUCI. Mr. Chairman, I cannot give you a definite answer on the time required. The only thing I can tell you for certain is that we are going in the right direction, because recently we have accumulated a number of small blocks of knowledge, which some people like to call breakthroughs. They are not breakthroughs, but small steps in research progress. You have heard about some of them; in recent weeks, for example, a part of the virus, the envelope, has been injected into monkeys. It has been shown that the monkeys make antibodies that can block the virus.

The next step will be to immunize chimpanzees who can be infected by the virus and then challenge the chimpanzees with the live virus to see if they are protected. If, in fact, they are protected from infection, that would be an important step. If it works—and the experiments are being done right now—then you will have the first important step toward developing a protective vaccine.

We we will not know the results of those studies until the middle or the end of this year. If, in fact, it works, we will go through very carefully designed studies to do further testing in the animal model and then move into some early human studies to determine if we have a safe and effective vaccine. I imagine we will not be to the point of testing in limited groups of people until 1988. If we are successful and a vaccine which in early tests is shown to be safe and to have some indications of efficacy, then you move into larger efficacy studies before you make it available to the general population. In those studies, you have to add on at least a couple of years because we are dealing with a disease whose incubation period is quite long.

We say we are optimistic; we mean we are optimistic because the scientific building blocks are being accumulated very rapidly. But, on the other hand, I will tell you that it will be several years before a vaccine will be available for the general population. The most realistic estimate of when a vaccine will be available will be, in fact, a long time, based on what we know now.

The **Chairman**. We know that there are current liability problems facing the pharmaceutical industry in developing these particular drugs. Can you give us your opinion as to what the willingness of the pharmaceutical companies is going to be to develop, produce, and assume the liability for an AIDS vaccine?

Dr. **MacDonald**. I do not know if I can speak for the pharmaceutical houses. There is interest, and there is great concern on their part related to the present liability situation.

Dr. Dowdle, do you want to comment further?

Dr. **Dowdle**. No, unless Harry has something to add.

Dr. **MacDonald**. Dr. Meyer.

Dr. **Meyer**. I would just say that again, it is going to take the data to see. What the risk would be of the vaccine will obviously influence how people will feel. And you have to develop the vaccine to see what types of risks there are associated with taking the vaccine to make a very good estimate about what the liability situation would be.

The **Chairman**. That is going to be a crucial consideration as the pharmaceutical companies get into this. People need to know that.

What is the current status of antiviral therapy?

Dr. **MacDonald**. Dr. Fauci.

Dr. **Fauci**. The status is that, as I mentioned to you, there are a number of agents that are in the process of being tested.

I think it is important for the committee to appreciate, Mr. Chairman, that there are no agents right now that have shown to be effective in clinically improving patients with AIDS. I think that is an important concept to keep in mind when you question as to whether there are patients in this country who do not have access to an effective agent. The answer is "No," because there are no effective agents. We are now trying to determine if there are any agents that are effective. A couple of them have shown that they can block viral transmissibility. But none of them have shown substantial, significant, or even approaching permanent clinical improvement in any individuals. We are moving as rapidly as possible to show if any agent or agents—there are several that are being tested—are both safe and efficacious.

The CHAIRMAN. What priority, Dr. MacDonald, have you given to antiviral research on AIDS?

Dr. MACDONALD. I am not sure what you are asking.

The CHAIRMAN. Well, how high a priority does antiviral research have among other AIDS concerns.

Dr. MACDONALD. Oh, yes, it has very high priority.

The CHAIRMAN. Is the priority high enough given the gravity of the disease and the problems that are involved?

Dr. MACDONALD. Well, I am not sure if you are talking budget priority or science priority. Science is moving rapidly. On the issue of budget, which I have not mentioned or brought up, we are instructing these gentlemen here—and they will get formal instruction at our AIDS task force meeting next Monday—that we need to relook at the budget and operating plan for 1988 and possibly some adjustment to fiscal year 1987 as well.

One of the things, I think, that we feel most proud of is that we have been able to readdress budget as the scientific opportunities change, as we did less than a year ago, and receive approval from the Department and OMB. There is much going on. I really cannot answer today, but to say that it is a good question, and we are hard looking at it.

The CHAIRMAN. OK.

Go ahead, Senator Nickles.

Senator NICKLES. Mr. Chairman, thank you very much.

I just have time for a quick question, but that does not mean that there is not a lot of interest, not only from this Senator, but a lot of others, on this issue.

Just quickly, is the AIDS epidemic increasing substantially, has it slowed down, or the rate of growth increased?

Dr. MACDONALD. Well, it is increasing rapidly, but the rate of doubling has slowed down. We were at one time talking about rates of doubling under a year, and now the rates are more in the range of 13 months. And we are hopeful that it will continue to slow, because of a number of things we are doing. The bloodborne AIDS, we hope will become a zero to very negative or very small problem in future numbers. And we are hoping that by the efforts of CDC and others in alerting people to responsible practices in high-risk groups, we will see slowing, also.

Senator NICKLES. But it is still doubling every 13 months?

Dr. MACDONALD. Is it every 13?

Dr. DOWDLE. Yes, approximately every 13.

Senator NICKLES. What is your estimate of the number of people who are infected with AIDS?

Dr. MACDONALD. It is a difficult number to give. The number that we use is the number you have heard frequently, of about 1 million people with antibody-positive status at this time, and all are potentially infected.

Senator **Nickles**. What is your estimate of the number of deaths per year?

Dr. **MacDonald**. In the March report, we exceeded 10,000 total deaths reported by CDC since the beginning. If we believe that this disease is uniformly or fairly uniformly fatal, then the reported deaths will follow that doubling pattern throughout the immediate future.

Senator **Nickles**. Do you think next year there could be 10,000?

Dr. **MacDonald**. Well, we have now reported 19,560 cases as of Monday, and we are estimating that 85 percent of those people will not be alive in 3 years; and then the numbers will continue to grow.

Senator **Nickles**. Geographically, has the distribution spread? I guess my impression is that it is more on the east and west coasts and so on—has it spread throughout the Midwest or not?

Dr. **MacDonald**. There are five States that dominate the picture so far: New York, Texas, Florida, California and New Jersey. But every State in the Union now has at least one reported case of AIDS, and we are concerned.

Senator **Nickles**. Have there been adequate funds given by Congress and directed by the administration toward the problem?

Dr. **MacDonald**. Yes; we think that the response of the Federal Government has been marvelous to date. But we are also well aware of the concerns that the last panel has addressed, and we think we need to relook at our numbers and priorities.

Senator **Nickles**. Thank you very much.

Senator Hatch, thank you.

The **Chairman**. Thank you, Senator Nickles.

How many product license applications or product license amendments have been received by the Office of Biologics in the last 12 months; do you have any idea?

Dr. **MacDonald**. Dr. Meyer?

Dr. **Meyer**. Let me answer that in a slightly different way, and then I will give you the exact answer.

The **Chairman**. Sure. That will be fine.

Dr. **Meyer**. Basically, at present, you have IND's for experimental products. There are 17 drugs that we would call immuno-stimulants that are currently under study under IND in this country. I think there are some eight that are antiviral that have been studied. One of them is temporarily not being studied because of toxicity, and looking for a different dosage.

Then in addition, you have some seven very important drugs that are being developed to treat the opportunistic infections that actually kill the AIDS patient.

So you have a large number of drugs that are currently under study in the United States We have only had one new drug application; that is the actual request for approval. That was for the drug, Isoprinosine—for use in pre-AIDS—which we turned down. We did not feel that the data submitted supported positive approval of that product. Experimental studies are still continuing.

The CHAIRMAN. Of these particular applications and/or amendments, how many of them have been approved, say, by April 1 of this year—or rejected? You have rejected the one, you say?

Dr. MEYER. There is only one application for approval for general use. There have been, as I indicated, many applications for experimental study. I gave you the number of drugs; the number of applications exceeds many times that. There are probably hundreds of individual applications from individual groups that are doing clinical studies that we have dealt with.

So we are very busy with those.

The CHAIRMAN. Is there only one that has been rejected so far?

Dr. MEYER. Only one has been rejected.

The CHAIRMAN. What is the reason for that?

Dr. MEYER. The data did not support the claim that the product was safe and effective.

The CHAIRMAN. Are there any product license applications or product license amendments that have been in the review process for more than 90 days?

Dr. MEYER. No; as I indicated, we have only had one product application for commercial use of a product, only one. The others, as Dr. Fauci said, are at the early experimental phase, and we have denied none of those, although there are several where we are waiting for additional information from sponsors.

Basically, we are giving top priority and special treatment to any drug that comes in for treatment of AIDS; they are handled individually. They are personally reviewed by me, on a regular basis, with all of my staff.

The CHAIRMAN. What has the FDA done to capitalize on or enhance the results of the NIH research?

Dr. MEYER. The thing that FDA has done is to work very closely with NIH and the academic community from the very onset. Our scientists are working day by day with Dr Fauci and his scientists. I am attending the meetings he is having; his people are attending the meetings we are having, so that there is no gap in information. We actually are helping often in testing drugs. For example, the drug Pentamidine, which was a very important drug to treat the opportunistic infections of AIDS, actually, the primary data generated to develop that drug was generated by CDC and by FDA in trying to speed it out.

So I would say we have hands-on involvement in trying to move things on with our sister agencies.

The CHAIRMAN. Has the FDA received any applications for confirmatory diagnostic tests?

Dr. MEYER. It depends on how you define a confirmatory diagnostic test. I would say we have received applications for modified versions or improved versions of diagnostic tests. All the tests that are actually out there now, some seven or eight, are all versions of the original ELISA test. We have several IND's that are currently going for tests that would be slight variations of that and might be improvements. We have others we know about that are coming that have not yet come to the IND stage that might be still greater improvement.

The CHAIRMAN. How soon might a confirmatory test be approved, say, for marketing purposes?

Dr. **Meyer**. It would depend upon the data we have. Let me stress, Senator, that the confirmatory test is not a safety issue. The confirmatory test is only useful to identify people who are not actually positive, in other words, people whose ELISA test has said they are positive, so you are screening their blood out. The confirmatory test just allows you to tell a person who has been incorrectly identified as being positive.

The safety of the blood supply has nothing to do with the confirmatory test.

The **Chairman**. What private sector initiatives have been undertaken in the area of AIDS public education and prevention, and how, if at all, are they coordinated with our government efforts?

Dr. **MacDonald**. I think I will—except for the comments I made in the opening remarks that we are dealing strongly with the Red Cross and other organizations—pass that to Shellie Lengel.

Ms. **Lengel**. We have worked with various organizations over the last 3 years in AIDS information and education. We have called together groups of people to enhance our efforts and worked with them in enhancing theirs.

The American Red Cross initiative probably is the one that is most important at this moment. We have three joint television public service announcements that are being released now, primarily aimed at quelling the rumors and panic associated with AIDS and promoting the Public Health Service Hotline which has been in existence for 3 years.

In addition, we have posters, radio public service announcements, and so on.

We also have put together a communications group comprised of people from various organizations around the country with an interest in AIDS, in order to keep up to date with what everyone is doing, so that we will not fall all over each other in duplicating efforts and filling gaps.

Dr. **MacDonald**. The CDC is also making a tremendous push in this area, and I think I would like Dr. Hopkins to respond also to the question.

Dr. **Hopkins**. I would just add to that and stress that we have been working with members of high-risk groups and organizations representing the various high-risk groups, as well as with representatives of health professional kinds of groups. It has been mentioned already here today that we are working with the National Hemophilia Foundation.

Also, one of the most important things we have been doing has been to help develop the guidelines for helping people in various situations to deal with AIDS. Among the groups which we have called in to consult with us on those have been various private sector organizations and interest groups as well.

The **Chairman**. OK. When we talk about AIDS public education and prevention programs, how much Federal money is allocated to such programs?

Dr. **MacDonald**. The CDC number, I think, is $25 million, isn't it?

Dr. **Hopkins**. Yes.

Dr. MacDonald. And for sake of completeness, and because of the importance, I do not want to leave out ADAMHA and its education program for drug users.

The Chairman. Sure.

Dr. Goodwin. Well, the drug abuse population, as Mr. Levi mentioned, one of the things we have to do is target to populations in their own language, in their own communities.

We intuitively are aware that public service announcements that are intended for the general public are not terribly useful when dealing with a specialized population like intravenous drug abusers. So, the efforts of the ADAMHA through the National Institute on Drug Abuse have been focused on targeting populations such as the shooting galleries and so forth. But clearly, here we have to work with the local communities, because local laws differ, local problems differ about this, and so what the ADAMHA has done is to coordinate through the PHS to reach these local groups, but by collaboration with local communities and groups that have had a long history of contact with these individuals.

The other area that we try to address is how to identify people through existing research techniques who are especially vulnerable to panic, because these become in a sense the panic spreaders.

It is important for people to be worried and concerned about the public health problems; it is destructive for people to panic. And there are some data bases already generated from other panic-type situations which the National Institute of Mental Health is exploring. But it is really a mixture of knowlege generation and trying to disseminate knowledge as quickly as we can.

The Chairman. OK. Let me go back to Dr. Hopkins.

Dr. Hopkins, at roughly $115,000 per grant, are the CDC's 1986 capacity-building grants to facilitate this expertise really sufficient to address the needs, particularly in areas where the incidence of disease is low and transmission could conceivably be slowed or stopped?

Dr. Hopkins. Mr. Chairman, we think it is important in trying to establish priorities for dispensing the grant moneys which have been made available to us. We think it is important both to augment areas which are heavily impacted since people do travel from those areas to other, lesser impacted areas, as well as develop in each of the areas where there has been to date much less of this disease, a basic capacity to allow people to assess their own local situation and begin putting in place health education and risk reduction programs.

We recognize also that while the Federal Government has a very important role of leadership, providing money, information, and in some instances people, to these communities, that the communities themselves, their own State and local governments, as well as the various private groups that have been mentioned, are also putting a substantial amount of funds into this.

We see basically a need to educate the general public about this problem, to allay some of the concerns—unsubstantiated concerns—related to the problem as well as have people understand the things that they really need to do to prevent transmitting this infection. We also see a need to get information out to high-risk groups as well as to the medical community itself.

The **Chairman**. All right. I have a whole raft of questions I am going to submit in writing. We now have a vote.

Dr. MacDonald, let me just ask one final question. Do you think we need a central AIDS information clearinghouse on the order of those already existing for cancer and other diseases, to coordinate and distribute AIDS education and prevention expertise? Do you think that might be something that needs to be done?

Dr. **MacDonald**. In my introduction, I introduced Dr. Dowdle, sitting on my right, who is now the Public Health Service AIDS Coordinator.

I think it is terribly important to have coordination of AIDS activities, and our effort, which we have tried to show today, demonstrates that we are working increasingly to coordinate that.

So we do have, in Ms. Lengel's office, a coordinating effort, and in Dr. Dowdle's. The importance of coordination cannot be overstated. We feel that we are doing a marvelous job now.

The **Chairman**. Do you think we need to go beyond that, though, and have a clearinghouse itself?

Dr. **MacDonald**. Well, we have hotlines. We have two hotlines in which information is processed, a third one coming on-line. We have one at CDC. There is a private hotline for drug users——

The **Chairman**. So you feel you are adequately addressing this under your present system?

Dr. **MacDonald**. Yes. But I must point out that we are reassessing constantly. The reason Dr. Dowdle is working, and we are meeting so frequently, is to keep looking.

The **Chairman**. You see, one of the things brought out here today by the first panel was that there is not enough dissemination of information, to the public as to the medical community. Maybe there is something more we need to do that might be done more effectively. Something that might bring greater public awareness of what the public really needs to know about AIDS. We would like to know as a committee whether we should do more in this area.

This committee always has a tendency to say that we should do more. That has been the nature of this committee for many years. My job as the chairman has been to make sure for the public at large and the taxpayers that, if we do more, that those funds are utilized in the best possible way, in the most efficient, reasonable, and effective way.

So I would like you to think about that question and give us the best advice you can on it. If we need to raise some more funds for that, I am not a bit against doing that. I think, though, we should not just throw money at these things. We have a big scare and everybody is concerned about it, as we should be, and I certainly am. The answer is not simply to throw money at AIDS, however. You have got to go at it the way Dr. Fauci has explained you are going at it, and it has got to be done in the best possible way.

So what we want is some guidance up here. If we have to get more money for AIDS, we may have to assess the whole public health budget and take the money from somewhere else. There just is not enough money out there to solve all the problems that we have in America. AIDS is an extremely critical and crucial problem. You have admitted yourself that if it is not our most important public health problem, it certainly is one of the most important public health problems.

I want to thank each of you for being here. I think this panel has added a lot to our knowledge. Your statement is an excellent one, and we will pay attention to that. Additional questions will be forwarded to you all for your respective comments.

I am going to recess, but first I will say that our next witness will be from the Department of Defense, Dr. J. Jarrett Clinton, Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance. In that position, Dr. Clinton has played an important role in formulating AIDS policy decisions of the Department of Defense, along with Dr. William Mayer, who could not be here with us today because of illness.

So we will begin with Dr. Clinton as soon as I get back from this vote on the floor, and that should certainly be I hope within 15 minutes.

So with that, we will recess until I can get back.

[Short recess.]

The CHAIRMAN. Dr. Clinton, you have waited a long time to give testimony. But we are putting your full statement in the record. I would like you to limit yourself to 5 minutes. I should have finished at 12 o'clock, really.

Please go ahead. We are delighted to have you here.

STATEMENT OF DR. J. JARRETT CLINTON, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR PROFESSIONAL AFFAIRS AND QUALITY ASSURANCE, DEPARTMENT OF DEFENSE

Dr. CLINTON. Mr. Chairman, I appreciate the opportunity to appear before this committee today and discuss the steps taken by the Department of Defense to protect our military personnel from acquired immune deficiency syndrome.

The initial policy statement signed by Secretary Weinberger in October of 1985 reflects our current understanding the natural history of this disease, the risk of transmission, the effect of infected individuals on the functioning of the military units, and the safety of the blood supply.

Our HTLV-III and AIDS policies are founded on three medical principles: Protect individuals deployable to areas with minimum medical support and severe endemic diseases, such as malaria; to protect the buddy blood donor system which may be required in battlefield conditions or contingency conditions; and to protect individuals required to receive essential live virus vaccinations, and I am particularly pointing to those that are not commonly used by civilians in the United States.

These policies have been adopted as an interim guidance and are reviewed continually. Let me summarize briefly the key components of our policy.

In July of 1985, our military blood collection organization initiated HTLV-III screening on all blood donations, concurrently with similar efforts in the civilian community.

In August of 1985, we required all civilian blood collection organizations operating on military installations to inform the cogizant local military medical officer of any positive finding of HTLV-III, as well as other specific infectious diseases.

In August of 1985, we required further all potential accessions, that is, recruits, to be screened for HTLV-III antibody prior to entry on service duty. Individuals who screened positive repeatedly on the enzyme immunoassay, that is, the ELISA, and have a positive immunoelectrophoresis, that is, the Western blot, are not eligible for military service.

In October of 1985, we required that Active duty and Reserve component military personnel be screened for the presence of HTLV-III antibody, using the following suggested priority order: first, individuals serving in or subject to deployment on short notice to areas of the world with a high risk of endemic disease such as malaria, or with minimal existing medical capability; second, individuals serving in or pending assignment to all other overseas permanent duty stations; third, individuals serving in units subject to deployment overseas; then other individuals or units deemed appropriate by the respective military departments—this might include health care workers; and finally, all remaining individuals in conjunction with routinely scheduled periodic physical examinations.

Individuals who are antibody-positive but manifest no evidence of progressive clinical illness nor immunological deficiency are retained in the military service. They receive a comprehensive clinical and immunological evaluation, are counseled on the risk of disease transmission, and informed that they are ineligible for blood donation—that is, ineligible to donate blood. Each individual will receive a comprehensive reevaluation at least annually. To protect the health and safety of infected individuals and of other military personnel, the services may limit the geographic assignment of these individuals having only HTLV-III positivity.

The medical assessment of each exposure to or case of HTLV-III infection includes an extensive epidemiological assessment of the potential transmission of HTLV-III to close personal contacts and family of the patient. This information is vital to provide appropriate preventive medicine counseling and to the continued development of scientifically based information regarding the natural history of the disease and the transmission patterns of this infection.

In support of the national effort to combat the problems of acquired immune deficiency syndrome and to answer questions regarding HTLV-III infection in the military environment, Congress mandated a Department of Defense AIDS research effort to be managed by the Assistant Secretary of Defense for Health Affairs.

In our policy guidance to the service most recently, we directed that research efforts emphasize the epidemiology and natural history of infection; rapid diagnosis; treatment and prevention in military environments; collaboration with other government agencies, particularly those of the Public Health Service and the Veterans' Administration; and to minimize involvement in basic drug and vaccine development, which is being done by other Federal agencies.

I want to emphasize that close coordination with the Public Health Service and their subgroups continues. At the request of the U.S. Public Health Service AIDS coordinator, official DOD representatives have been nominated to serve on five of those AIDS subgroups.

In summary, the Department of Defense has initiated a medically sound surveillance program, both of potential recruits and of active duty personnel. This carefully designed program will minimize the introduction of the infection into our community and promote containment of the infection in the event that an active duty member has the HTLV-III infection.

We have taken vigorous precautions to protect the current blood bank and the safety of our potentially needed buddy blood donor bank system. We are actively engaged in personal counseling and public information to minimize the potential transmission of infections in our active duty members and their families.

Our medical assessment and treatment protocols for those with active ARC or AIDS utilizes our finest medical facilities and extensive collaboration with agencies and scientists outside the Department of Defense.

Our research efforts, though modest, are directed primarily to topics of epidemiology, early treatment and identification, prevention, and other topics of special interest to the military.

We believe, therefore, that we have constructed a balanced, comprehensive, medically sound effort to combat this disease. Our collaborative efforts with other Federal efforts, particularly those of the Public Health Service, should indeed contribute significantly to the overall U.S. initiatives against this disease.

I would be pleased to answer any questions you have, Senator.

The CHAIRMAN. Thank you Dr. Clinton.

I am going to submit questions to you. I have a number of questions that I particularly want to button down for our hearing record. We appreciate the excellent statement you have given, and the excellent efforts you are making in the military. I think it is a tribute to the Department of Defense and your leadership in this area.

Dr. CLINTON. Thank you.

The CHAIRMAN. Thank you so much for being with us.

[The prepared statement of Dr. Clinton and responses to questions submitted by Senators Hatch and Kennedy follow:]

STATEMENT

HONORABLE J. JARRETT CLINTON, M.D.

DEPUTY ASSISTANT SECRETARY OF DEFENSE
(PROFESSIONAL AFFAIRS & QUALITY AFFAIRS)

ACQUIRED IMMUNE DEFICIENCY SYNDROME

before the

Committee on Labor and Human Resources
United States Senate
99th Congress

April 16, 1986
9:30 a.m.

Not for Publication
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United States Senate

I appreciate the opportunity to appear before the Committee on Labor and Human Resources today to discuss steps taken by the Department of Defense to protect our military personnel from what we consider to be a serious public health problem - Acquired Immune Deficiency Syndrome (AIDS). The Department of Defense is vitally concerned with protecting all military personnel from the risk of infection with the Human T-Lymphotropic Virus Type III (HTLV-III) which is associated with AIDS, and with providing compassionate counseling and treatment to its victims. Our HTLV III screening measures have been established to protect individuals who are required to receive essential live virus vaccinations, protect individuals deployable to areas with minimal medical support and severe endemic diseases such as malaria, and to protect the buddy blood donor system which may be required in battlefield conditions.

Given these concerns, it was imperative that the Department move quickly to identify HTLV-III infection among our troops, and we have taken decisive action. The initial policy statement, signed by Secretary Weinberger in October 1985, reflects our current understanding regarding the natural history of this disease, the risk of transmission to noninfected personnel, the effect of infected individuals on the function of the unit, and the safety of the blood supply. It has been adopted as interim guidance which is reviewed continually. I will summarize briefly several key aspects of our policy.

The military blood collection organization initiated the screening of blood donations for HTLV-III antibody on July 1, 1985, concurrently with their civilian counterparts. On August 14, 1985, we required all blood collection operations functioning on military installations, civilian as well as military, to inform the cognizant local military medical authority of any positive findings indicative of the presence of hepatitis-B surface antigen, HTLV-III antibody and syphilis in blood donated by active duty personnel.

Currently, DOD Military Blood Program Office policies and Food and Drug Administration guidelines are followed by the Military Departments' Blood Programs and by civilian blood agencies collecting blood on military installations. In the event that units of blood are not screened for infectious agents prior to transfusing in contingency or battlefield situations, the DOD Military Blood Program Office in coordination with the Military Departments will provide guidance to operational units to ensure that potential donors have been screened.

On August 30, 1985, the Deputy Secretary of Defense signed a memorandum requiring all potential accessions to be screened for HTLV-III antibody prior to entry on active duty. Applicants for enlisted service are screened for exposure to HTLV-III at the Military Entrance Processing Station or the initial points of entry to military service. Candidates for officer service are screened for exposure to HTLV-III during their pre-appointment or pre-contracting physical examinations. Individuals confirmed as HTLV-III antibody positive - those who screen positive on at least two Food and Drug Administration approved enzyme immunoassay (EIA) serologic tests and also have a positive immunoelectrophoresis test (Western blot) - are not eligible for military service.

On October 24, 1985, the Secretary of Defense required that active duty and reserve component military personnel be screened for the presence of HTLV-III antibody using the following suggested priority order: individuals serving in or subject to deployment on short notice to areas of the world with a high risk of endemic disease or with minimal existing medical capability; individuals serving in or pending assignment to all other overseas permanent duty stations; individuals serving in units subject to deployment overseas; other individuals or units deemed appropriate by the respective Military Department; and, all remaining individuals in conjunction with routinely scheduled periodic physical examinations.

Individuals who are antibody positive but manifest no evidence of progressive clinical illness or immunological deficiency are retained. They receive a comprehensive clinical and immunological evaluation and are counseled on the risks of disease transmission, methods of prevention, and informed that they are ineligible to donate blood. Additionally, each individual will receive a comprehensive re-evaluation at least annually. The Service Secretaries, in order to protect the health and safety of infected individuals and of other military persons, may limit assignment of such individuals with respect to the nature and location of the duties performed in accordance with operational requirements.

The medical assessment of each exposure to or case of HTLV-III infection includes an epidemiological assessment of the potential transmission of HTLV-III to close personal contacts and family of the patient. This information is vital to provide appropriate preventive medicine counseling and to the continued development of scientifically based information regarding the natural history and transmission pattern of HTLV-III. Therefore, results obtained from laboratory tests for HTLV-III and information concerning personal drug use or consensual sexual activity disclosed by a service member as part of an epidemiological assessment may not be used against him or her in actions under the Uniform Code of Military Justice, in a Line of Duty determination, or on the issue of characterization in separation proceedings. Such information may not be used as the basis for separation of the Service member except for a separation based upon physical disability or for the convenience of the government.

Each military medical service will conduct ongoing clinical evaluations of each antibody positive individual's health status at least annually, provide appropriate preventive medicine counseling to individual patients, provide public health education materials to the beneficiary population, conduct longitudinal epidemiologic evaluations of antibody positive individuals, and prepare internal reports to facilitate timely review and reassessment of current policy guidelines. Reviews of the natural history and epidemiology of this disease in military populations will provide valuable information to enable us to fine tune Department policy.

In support of the national effort to combat the problems of Acquired Immune Deficiency Syndrome (AIDS) and to answer unique problems of HTLV-III infection in military environments, Congress mandated a Department of Defense AIDS research effort to be managed by the Assistant Secretary of Defense (Health Affairs). This Tri-Service program will be administered by the Department of Army as lead agency for infectious disease research. This January, the Assistant Secretary of Defense (Health Affairs) issued guidance on the content of the DoD AIDS Research Program and established an AIDS Research Policy Committee. Coordination with the NIH AIDS research program has been established and cooperative efforts were included in the DoD guidance. In policy guidance to the Services, we directed that research efforts emphasize epidemiology and natural history of infection; rapid diagnosis, treatment and prevention in military environments; participation by other government agencies (AFIP and USUHS); and, colloboration with NIH AIDS treatment and evaluation programs, but not involvement in basic drug and vaccine development. To ensure a program continuum, we also directed that the Department of Army provide adequate FY 88-92 funding of Tri-Service requirements for the DoD AIDS research program.

Close coordination with the Public Health Service AIDS activities continues. At the request of the USPHS AIDS coordinator, official DOD representatives have been nominated to serve on the Blood and Blood Products, Epidemiology and Disease Prevention, Psychological and Addictive Matters, Vaccine Development and Therapy, and Education and Health Promotion USPHS AIDS sub-groups. Additionally; Dr. Walter Dowdle, the current USPHS AIDS coordinator, has been nominated to serve on the Armed Forces Epidemiological Board, our principal civilian advisory group for all infectious disease issues of military importance, including HTLV-III.

Due to the potential impact of HTLV-III transmission on the battlefield through blood transfusions and the worldwide dispersal of our troops with concomitant exposure to diseases not experienced in North America, the Department has taken the lead in disease surveillance and preventive medicine aspects of the natural history of AIDS. We need to know much more about the disease including how it is transmitted, and how it might be controlled.

The Department of Defense will not allow the threat of AIDS to go unchecked among military personnel. We have taken decisive action to prevent anyone who has been exposed to HTLV-III from entering the Services. We are screening the entire force to identify and track all HTLV-III positives and separate those who evidence progressive clinical illness. We will review our current policy continually to determine if refinements are needed. We are committed to taking whatever steps are necessary to protect the readiness of our troops.

This concludes my prepared statement. I would be pleased to respond to any questions you might have.

RESPONSES BY DR. J. JARRETT CLINTON

SENATOR HATCH'S QUESTIONS

1. Dr. Clinton, I'd like to get some idea of how serious a problem AIDS has been for our military establishment. How many cases of AIDS have been identified among defense department personnel over the last five years or for any other period for which data are readily available?

Answer: The occurrence of HTLV-III infections is an important consideration for the Department from a mission perspective, from the perspective of the infected individual, and from a medical resource perspective. Results from the Military blood program screening for October through December 1985 show a Western blot confirmed HTLV-III antibody positive rate of 0.55 per 1000 donors (25 of 44,968 donors screened). This is about one positive unit per 1800 units of blood tested. As of December 1985, 116 service personnel have been diagnosed with AIDS and 90 with ARC. As of March 1986, approximately 305,700 potential recruits were screened with a Western blot confirmed HTLV-III antibody positive rate of 1.5 per 1000 potential applicants.

2. What, if any, effort is the Defense Department making to educate servicemen about the dangers of contracting AIDS? For instance, is information about AIDS currently being included in the briefings about venereal disease that troops traditionally receive at the unit level?

Answer: Development of information resources on HTLV-III infection has been under the auspices of the Health Affairs sponsored ad hoc Tri-Service HTLV-III education and information committee. All three medical services have disseminated educational packages to their medical treatment facilities for use in general education and individual counseling settings.

3. Mrs. Kushnick in her written testimony questioned the effectiveness of your HTLV-III antibody test on grounds that the antibodies that this test measures may not appear in the blood for 11 months after infection with the virus and that there is no way to know how many of the people who come out positive in this test will go on to get AIDS. What is your response to these statements, Dr. Clinton?

Answer: There are theoretical limitations to our testing. However, the sensitivity and specificity of repeated enzyme linked immunosorbent assays coupled with immunoelectrophoretic confirmation conducted under a standardized protocol is state of the art. Antibody screening is followed by extensive clinical evaluation and determination on an individual basis of the health status of the individual and his or her fitness for continued service. The clinical evaluation of HTLV-III positive individuals is repeated annually. Finally, our clinicians are alert to the presenting symptoms of ARC and AIDS and will examine thoroughly any patient with these symptoms even though a recent HTLV-III screening may have been negative.

4. Have the blood screening programs you initiated last year resulted in any lessening of the incidence on new AIDS cases among servicemen?

Answer: HTLV-III antibody screening is a tool for the identification of cases of HTLV-III infection. Except for eliminating infection secondary to blood transfusions, screening alone will not lessen the incidence of infection in the short term. We believe, however, that better understanding of the epidemiology of the infection and responsible action by infected individuals eventually will have an impact on decreasing the incidence of infection.

5. How foolproof are these screening programs. For instance, is it possible to ensure every serviceman that he will not contract AIDS through contaminated blood received in a battlefield transfusion?

Answer: No program is foolproof. The goal is to take action to minimize the risk of Service related activities causing additional harm to the infected individual and to minimize the potential transmission of this virus in contingency situations.

SENATOR KENNEDY'S QUESTIONS

1. As I understand current DoD guidelines, Dr. Mayer, the Armed Forces is currently serologically screening all new recruits for AIDS, and rejecting all those with a positive test. Is that right?

Answer: We are testing all recruits for HTLV-III antibodies. If these antibodies which indicate infection, but not necessarily AIDS, are confirmed, the recruit is rejected.

2. Are records kept of recruits who test positive?

Answer: Records are maintained by the Defense Manpower Data Center on all recruit applicants.

3. Can you tell us what the results of the initial screening are? How many new recruits are antibody positive?

Answer: Yes. Over the first six months (Oct 85- Mar 86), approximately 305,700 potential applicants were tested. The prevalence of repeated reactive ELISA and Western blot confirmed HTLV-III antibody positive individuals among this group was 1.5 per thousand tested.

4. The Armed Forces is also conducting mass screening of all active duty personnel for AIDS, with individuals testing positive, but disease free, being retained in the service while those positive with evidence of disease receiving honorable but automatic discharges along with medical treatment and counseling. Is that correct?

Answer: No. Individuals who are infected with HTLV-III and demonstrate progressive clinical illness are referred for medical evaluation for a determination of fitness for continued service in accordance with Title 10 United States Code Section 1201, et seq. There is no policy of automatic discharge.

5. How will the confidentiality of those testing positive be protected?

Answer: We have taken steps through the automated reportable disease database to protect and restrict access to this information so that only those with a need to know will have access to the information. For example, in order to assure timely followup evaluations, certain medical personnel must have access in order to schedule such evaluations.

6. Are screening and follow-up policy the same in all three services? If not, why not?

Answer: Yes. Guidance for screening requirements, laboratory tests, and clinical evaluation was developed by Tri-Service working groups and communicated to the Secretaries of the Military Departments by memoranda from Dr. Mayer.

7. How does testing help the asymptomatic patient?

Answer: Case identification is an important tool in the prevention of additional cases of HTLV-III infection and to ensure the best medical outcome for infected individuals.

Individuals who are aware of their infected status can take personal responsibility to prevent the transmission of the virus through sexual contact, to unborn children, and by not donating blood, blood products, or other tissues that may be infective.

Individuals who are infected can protect their own health by alerting their physician to their status, by the early diagnosis and treatment of secondary infections that are treatable, and by the avoidance of situations such as exposure to severe infectious disease that may compromise their health status.

8. Considering the association between AIDS and certain risk groups, will the Armed Forces press active duty personnel who test POSITIVE but are disease free about the source of their exposure?

Answer: As part of the epidemiological evaluation, active duty personnel will be asked questions pertaining to the source of their infection. The DoD has, however, issued policy that no punitive action may be taken based on the revelation of homosexual or illicit drug use revealed as part of this evaluation.

9. Is there concern at the DoD that penalties such as automatic discharge will hinder the willingness of personnel to be candid?

Answer: There is no policy of automatic discharge.

10. Has the DoD invested in providing resources for counseling and treating antibody positive individuals who have no symptoms?

Answer: The military medical services have established extensive support systems to provide physical and psychological support to all individuals infected with HTLV-III.

11. Has the DoD established the cost of the screening program for active duty personnel?

Answer: The approximate cost per individual for HTLV-III antibody determination is five dollars.

12. Will the screening program draw funds away from other important medical needs?

Answer: HTLV-III infection is an emerging epidemic with global implications. The HTLV-III surveillance program is an important component of the total health care program of the DOD. We believe that our surveillance program can be accomplished with current funds without jeopardizing other important medical needs.

13. Does the military have their own blood bank supplies?

Answer: The military blood program is 98 percent self-sufficient.

14. What will be the course of action regarding military status for military personnel found to be AIDS positive during blood donation?

Answer: All blood collection agencies functioning on military installations, civilian as well as military, are required to inform the military medical authorities of any positive findings indicative of the presence of an infectious agent (hepatitis-B surface antigen, HTLV-III antibody, syphilis) in blood donated by military personnel. All individuals confirmed as HTLV-III antibody positive are medically evaluated to determine the status of their infection and their fitness for duty.

15. What is a "battlefield transfusion?"

Answer: Whole blood transfused during contingencies may only be typed and cross-matched, not screened for the presence of infectious agents such as HTLV-III. This is the scenario implied by the term "battlefield transfusion".

16. When did the last one occur?

Answer: The last ones were in Beirut, and Grenada. Additionally, there are numerous examples of "buddy" blood donations on board U.S. ships. For example, in November of 1983, the U.S.S. Kennedy was in the Meditarranean. During flight operations, a Navy pilot crashed in the water. The individual was transfused with 14 units of blood obtained directly from ship mates.

17. In a worst case situation, what would be the probability of receiving an HTLV-III transfusion?

Answer: All technologies known to us are being utilized to avoid an HTLV-III transfusion.

Given the current safety of our blood supply and the soon to be realized identification of active duty members known to be HTLV-III positive, we believe that the probability of an HTLV-III contaminated transfusion is remote.

18. Will AIDS patients in military hospitals be isolated? What about during in-hospital testing of antibody positive personnel without symptoms? How will confidentiality be maintained while on this AIDS ward?

Answer: The infection control recommendations of the U.S. Public Health Service are followed by all military medical treatment facilities. It is not necessary to post the patient's diagnosis or separate patients into isolated wards. Rather the necessary precaution for potential exposure to blood-borne infections must be followed.

19. I understand there are plans to restrict stations for antibody positive personnel without symptoms. Why do that if personal contact carries no risk?

Answer: Responsibility for assignment policy was delegated to the Secretaries of the Military Departments by the Secretary of Defense and may reflect broader concerns that address other factors such as potential exposure to serious infectious diseases and potential political concerns raised by less-well informed foreign governments in addition to strictly medical considerations.

The CHAIRMAN. We will move to our last panel, which is composed of witnesses from academic institutions and the private sector who will further provide perspectives on AIDS public health issues and the medical economics of AIDS.

Dr. Harvey Fineberg is dean of the Harvard School of Public Health, and we are very happy to have him with us.

Dr. Anne Scitovsky, is chief of the Health Economics Department of the Palo Alto Medical Foundation and Research Institute.

And Ms. Barbara Lautzenheiser is a consultant for Trans America Occidential Life Insurance Co.

We are pleased to have all of you with us today. Thank you for sharing your expertise with us.

Dr. Fineberg, I understand that you have to catch a plane, so we are going to proceed with you. We would like you to each keep your statements, if you can to even less than 5 minutes in length. We will put your written statements in the record. I will submit written questions to you. It is important that what you have to say be included in the record I appreciate the excellent statements you have prepared.

Dr. Fineberg, we will turn to you.

STATEMENT OF DR. HARVEY V. FINEBERG, DEAN, HARVARD SCHOOL OF PUBLIC HEALTH; DR. ANNE SCITOVSKY, CHIEF, HEALTH ECONOMICS DEPARTMENT, PALO ALTO MEDICAL FOUNDATION AND RESEARCH INSTITUTE, AND BARBARA LAUTZENHEISER, CONSULTANT, TRANS AMERICA OCCIDENTAL LIFE INSURANCE CO.

Dr. FINEBERG. Mr. Chairman, it is an honor for me to have this opportunity to testify before you. I appreciate your understanding of my time constraint, but I should add that there is another plane, and I am at your disposal for as long as you feel it will be helpful.

The CHAIRMAN. Thank you.

Dr. FINEBERG. The main point I would like to make, Mr. Chairman, is that we do know enough about AIDS to take effective action today. We cannot cure the disease. We cannot halt progression once infection has occurred. We do, however, understand enough about the cause and spread of AIDS to give people the knowledge they need to protect themselves.

This cannot and will not happen with a conventional approach. What is needed is a massive, unprecedented educational effort aimed both at the general public and at high-risk groups, intended both to stop the spread of disease and to quell the wave of public hysteria it has left in its wake.

As you have heard, perhaps 1 million Americans already are infected with the AIDS virus, and are believed capable of transmitting it to others. Only a small fraction of those infected have developed clinical disease. We do not know the identities of most of these symptom-free carriers. Neither do they. And neither do their sexual partners.

Despite the best efforts of the scientific community, biomedical research cannot eliminate the problem of AIDS in the short term. Even if a vaccine were created tomorrow, testing for safety and effectiveness would consume at least several years, and there is no certainty that a safe and effective vaccine can ever be developed.

Successful drug therapy would require both killing all virus, which we know invades the brain, an area that is protected from many drugs, and reconstituting the patient's damaged immune system. These are formidable requirements, unlikely soon to be met.

The fact is, though, we require no new technological breakthroughs to stop the spread of the AIDS virus. The virus is transmitted as a consequence of personal behaviors, primarily through sex practices that involve exchange of bodily fluids and sharing of contaminated needles.

In principle, every uninfected individual with adequate information can exert personal control to avoid contracting AIDS, and every infected individual can exert personal control to avoid spreading AIDS. We can combat AIDS successfully if we choose to do so, through information, education and voluntary behavior change.

We need to think about educating the public in the health area in a wholly new way—more like a private corporation uses commercial marketing of a new product. In public health, the health of the American people is our product.

Recently, when the Polaroid Corp. introduced a new camera, its Spectra System, the company reportedly will invest more than $30 million to make this one product known to the buying public. When Procter & Gamble introduced new Liquid Tide, a product with a name already familiar to households throughout America, the company mounted a new $50 million to $60 million promotional campaign. The AIDS epidemic, in modern times, is an unprecedented threat to health that warrants a major campaign of accurate, creatively designed communication to the public and to high-risk groups.

A comprehensive education effort on AIDS could effectively use $50 million to $75 million per year over the next 2 years. By contrast, the Federal Centers for Disease Control has available this year only $16.5 million to support all of its externally funded education and risk reduction efforts.

The public education campaign about AIDS should be based on a comprehensive communication strategy, including extensive use of electronic mass media. At the present time, the Centers for Disease Control is not permitted to spend one dime to purchase time on radio or television to provide the public with information that could help stop the spread of AIDS.

Senate bill S.1430, introduced by Senator Moynihan, and legislation drafted by Senator Kennedy to improve education on AIDS are important steps in the right direction; but the proposed annual authorizations should be substantially increased and authority should be granted to purchase radio and television time.

All members of the public need to know enough about AIDS to make informed decisions about their behavior. Everyone should know that a stable, mutually monogamous relationship with an uninfected person eliminates any risk of sexual transmission of the AIDS virus.

Everyone should realize that the donor of blood has absolutely no risk of contracting AIDS from that life-sharing act.

It is especially important to mount intensive educational efforts about AIDS in our public schools. Every youth old enough to engage in sexual relations or to experiment with intravenous drugs needs already to have been educated about AIDS.

Reaching high-risk groups in an effective manner will require special effort and ingenuity. Intravenous drug users, for example, about whom we heard a bit earlier, are the most neglected high-risk group and pose the greatest threat of transmitting the AIDS virus to the public at large.

The majority of AIDS cases in children, for example, occurs in infants, where the only identifiable risk factor was that the mother was an intravenous drug abuser.

To combat a disease problem the magnitude of AIDS will require all the imagination, energy and know-how we can muster from the public and private sectors. A comprehensive strategy to deal with AIDS will have many components.

My plea to you today is that we invest adequate sums to make effective use of the tool we already have available—education and effective communication to inform everyone about the disease and its risks and to produce behavior change that will ultimately reduce the burden of AIDS on the American people.

Thank you very much.

The CHAIRMAN. Thank you, Dr. Fineberg.

[The prepared statement of Dr. Fineberg follows:]

Statement by:

Harvey V. Fineberg
Dean
Harvard School of Public Health

Before the Senate Committee on Labor and Human Resources

April 16, 1986

Mr. Chairman, distinguished Senators, it is an honor for me to have this opportunity to testify before you.

We know enough about AIDS to take effective action today. We cannot cure the disease. We cannot halt progression once infection has occurred. We do, however, understand enough about the cause and spread of the AIDS virus to give people the knowledge they need to protect themselves. This cannot happen with a conventional approach. What is needed is a massive, unprecedented educational effort aimed both at the general public and at high-risk groups, intended both to stop the spread of disease and to quell the wave of public hysteria it has left in its wake.

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Despite the best efforts of the scientific community, biomedical research cannot eliminate the problem of AIDS in the short term. Even if a vaccine were created tomorrow, testing for safety and effectiveness would consume at least several years, and there is no certainty that a safe and effective vaccine can ever be developed. Successful drug therapy would require both killing all virus, which we know invades the brain--an area that is protected from many drugs--and reconstituting the patient's damaged immune system. These are formidable requirements, unlikely soon to be met.

The fact is, though, we require no new technological breakthroughs to stop the spread of the AIDS virus. The virus is transmitted as a consequence of personal behaviors--primarily through sex practices that involve the exchange of bodily fluids and the sharing of contaminated needles. In principle, every uninfected individual, with adequate information, can exert personal control to avoid contracting AIDS. And every infected individual can exert personal control to avoid spreading AIDS. We can combat AIDS successfully _if_ we choose to do so, through information, education, and voluntary behavior change.

We need to think of educating the public about health in a wholly new way, more like a private corporation views the commercial marketing of a new product. In public health, the health of the American people _is_ our product. Recently the Polaroid Corporation introduced a new camera, its Spectra System, and the company reportedly will invest more than 30 million dollars to make this one product known to the buying public. When Procter & Gamble introduced new Liquid Tide, a product with a name already familiar to households throughout America, the company mounted a new 50 to 60 million dollar promotional campaign. The AIDS epidemic, in modern times, is an unprecedented threat to health that warrants a major campaign of accurate, creatively designed communication to the public and to high risk groups.

A comprehensive education effort on AIDS could effectively use 50 to 75 million dollars per year over the next two years. By contrast, the federal Centers for Disease Control has available this year only $16.5 million to support all of its externally funded education and risk-reduction efforts. The public education campaign about AIDS should be based on a comprehensive communication strategy, including extensive use of electronic mass media. At the present time, the Centers for Disease Control is not permitted to spend one dime to purchase time on radio or television to provide the public with information that could help stop the spread of AIDS. Senate bill S.1430, introduced by Senator Moynihan, and legislation drafted by Senator Kennedy to improve education on AIDS are important steps in the right direction, but the proposed annual authorizations should be substantially increased, and authority should be granted to purchase radio and television time.

All members of the public need to know enough about AIDS to make informed decisions about their behavior. Everyone should know that a stable, mutually monogamous relationship with an uninfected person eliminates any risk of sexual transmission of the AIDS virus. Everyone should realize that the donor of blood has absolutely no risk of contracting AIDS from that life-sharing act.

It is especially important to mount intensive educational efforts about AIDS in our public schools. Every youth old enough to engage in sexual relations or to experiment with intravenous drugs needs already to have been educated about AIDS.

Reaching high-risk groups in an effective manner will require special effort and ingenuity. Intravenous drug abusers, for example, are the most neglected high-risk group and pose the greatest threat of transmitting the AIDS virus to the public at large. This high-risk group includes streetwalker prostitutes, many of whom turn to prostitution to support their drug habits, and heterosexual men who are spreading the virus to their partners, who in turn can transmit it to others. The majority of AIDS cases in children occurs in infants where the only identifiable risk factor is that the mother was an intravenous drug abuser. To reach addicts, we need an aggressive outreach campaign that goes beyond pamphlets and posters to include face-to-face meetings in which information can be exchanged and the addicts' questions can be answered. Intravenous drug abusers should be counseled to enroll or continue in treatment programs to eliminate abuse of intravenous drugs. The federal government has within its power to expand the availability of methadone treatment to heroin addicts by increasing support of available treatment programs and by enabling more physicians to prescribe methadone.

To combat a disease problem the magnitude of AIDS will require all the imagination, energy, and know-how we can muster from the public and private sectors. A comprehensive strategy to deal with AIDS will have many components. My plea to you today is that we invest adequate sums to make effective use of the tool we already have available--education and effective communication to inform everyone about the disease and its risks, and to produce behavior change that will ultimately reduce the burden of AIDS on the American people.

* * * *

The CHAIRMAN. Dr. Scitovsky, we will turn to you.

Dr. SCITOVSKY. Mr. Chairman, I am pleased to have the opportunity to participate in this hearing on AIDS, and shall talk briefly about the studies we have conducted on the cost of treatment of AIDS.

In addition to the oral statement I am presenting, I have also submitted a somewhat larger, detailed statement.

The CHAIRMAN. We will place both in the record.

Dr. SCITOVSKY. And I have more information if it should be desired.

Since early 1985, I have done some studies on medical care costs of AIDS patients. Despite the general concern over the financial burden the AIDS epidemic is imposing on its victims, society in general, and especially on the metropolitan communities where the disease has been centered so far, data on medical care costs of AIDS are very scarce. It is surprising, but they are very scarce and hard to get hold of.

The most widely publicized figure is an estimate of the lifetime costs of the first 10,000 AIDS cases, made by Dr. Ann Hardy of the Centers for Disease Control in early 1985—quite early in the course of the epidemic. She made an estimate of lifetime hospital costs of $147,000 per case.

This estimate has gained very wide publicity.

It is quoted everywhere—although it was admittedly, according to Dr Hardy's own statement in the article which was finally published in the Journal of the American Medical Association in January, 1986—based on very limited data.

To date we at the Palo Alto Medical Foundation and also at the Institute for Health Policy Studies at UC/San Francisco have completed two studies on medical care costs of AIDS. One is a detailed retrospective study of medical care costs of AIDS patients treated at San Francisco General Hospital in 1984. The second, based on cost data from around the country—not solely on San Francisco, which is very special when it comes to cost of treatment—estimates the nationwide medical care costs of AIDS in 1985, 1986, and 1990. These estimates were made at the request of the Centers for Disease Control, who gave us a contract to do the study and who supplied us with the estimates of the number of AIDS cases alive at any time during these 3 years.

Finally, another more comprehensive, prospective study of the cost of treatment of AIDS patients in San Francisco not only at San Francisco General Hospital, but also at the Kaiser Permanente Health Plan and by community physicians who are participating in the study, is currently underway.

Our study conducted at San Francisco General Hospital showed considerably lower costs of treating AIDS patients than had been indicated by previous estimates, notably that of Dr. Hardy. For example, we found that the lifetime, inpatient costs of an AIDS patient who received all his hospital care at San Francisco General Hospital from diagnosis of AIDS to death was around $30,000 as compared to Handy's estimate of $147,000. The principal reason for the lower costs we found in San Francisco, at San Francisco General Hospital, was the much lower use of hospital services in San Francisco, especially much shorter hospital stays.

While the average length of hospital stay for an AIDS patient in San Francisco was then about 12 to 13 days, it is now around 11 days. Data from other areas indicate that it ranges from 12 to 72 days, with a clustering around 15 to 25 days.

But even allowing for the special conditions in San Francisco that permit a lower use of hospital services, I think the Hardy estimate is too high. Evaluating all the data I have been able to assemble from around the country—and as I said before, they are scarce—I would say the lifetime direct medical care costs of an AIDS patient are at the very most around $90,000, to 100,000, but I think more likely around $60,000 to $70,000.

For the Centers for Disease Control, I made a range of estimates of the direct medical care costs of AIDS in the United States in the 3 years for which they provided us with prevalence data. For 1985, they gave us one figure; for 1986, they gave a low and a high prevalence estimate, and for 1990, they also gave a low and a high estimate.

For my best estimate—I made five estimates, ranging from very low, based more or less on San Francisco data, which would show what, under the best conditions, medical care costs could come to, to very high, where I used the highest variables on average length of hospital day, average charge per hospital day, average number of admissions per case per year, and average outpatient charges. But I figured my medium estimate is about the best.

For 1985, my best estimate is $517 million in 1984 dollars. For 1986, using the low CDC estimate, my best estimate is $870 million, and using the high CDC estimate, it is $1 billion—again in 1984 dollars.

I shall refrain from giving the estimates for 1990. I feel making estimates that far in advance, given the enormous difference between the CDC low and high prevalence estimate for that year, are really quite fruitless

To give these estimates some perspective, I think they should be set within the framework of other health care expenditures. As a percentage of total personal health care expenditures, they are a fraction of 1 percent, ranging from one-tenth of 1 percent to nine-tenths of 1 percent for my low and high estimates, respectively.

They are also considerably less than the direct medical care expenditures for other diseases. To cite just a few, in 1981, Medicare reimbursements for patients with end-stage renal disease amounted to $1.5 billion. This is in 1981 dollars, considerably lower than 1984. As another example, medical care costs of persons injured in motor vehicle accidents have been estimated to have amounted to $3.3 billion in 1980 dollars.

This is not to belittle the costs of the AIDS epidemic, which are high. But I believe exaggerating the medical care costs of the AIDS epidemic does a disservice to the persons with AIDS and adds to the hysteria about the epidemic. I am very concerned about the very high estimates that are regarded as carved in stone: this is the cost. I think we need more extensive studies of what are the actual costs.

To sum up, I think some of the estimates, are too high. In addition, there is some evidence that costs of treatment have been coming down a little. Average length of hospital stay seems to have declined everywhere, not only in San Francisco. I have data from Los Angeles that show a drop from 19 days to 17; at M.D Anderson Hospital in Houston, TX, it has come down from 30 days to 15 days, according to a personal communication from the physician who treats most of the AIDS cases there.

In addition, there is also evidence that the use of intensive care has diminished as it becomes more apparent that in many cases, intensive care prolongs dying rather than living; intensive care is a brutal process and should be used sparingly.

Nevertheless, it is clear that the AIDS epidemic imposes a severe strain on the medical resources of the metropolitan centers where the epidemic has been concentrated so far, especially on their public hospitals.

This makes it essential to devise alternatives to inpatient care, to the extent that this is medically feasible. San Francisco has shown that it can be done to quite an extent.

I therefore strongly support Senator Kennedy's proposal, which among other goals would seek to encourage the development of comprehensive outpatient services for persons with AIDS by making grants to public and nonprofit, private community entities.

Judging by what I have observed in San Francisco, I would say it is not only feasible to do this. It would not only reduce costs, but would also provide very much more humane treatment of patients.

Thank you very much.

The CHAIRMAN. Thank you, Dr. Scitovsky.

[The prepared statement of Dr. Scitovsky, and responses to questions submitted by Senators Hatch and Kennedy follow:]

STATEMENT BY

ANNE A. SCITOVSKY

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BEFORE THE

U.S. SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
HONORABLE ORRIN G. HATCH, CHAIRMAN

WEDNESDAY, APRIL 16, 1986

My name is Anne Scitovsky I am the chief of the Health Economics Department of the Palo Alto Medical Foundation, in Palo Alto, California, and a lecturer at the Institute for Health Policy Studies of the University of California, San Francisco I am pleased to have the opportunity to participate at this hearing on the effects of our national effort in AIDS research, prevention and treatment

Since early 1985, I have been studying the medical care costs of AIDS patients Despite the concern over the financial burden the AIDS epidemic imposes on its victims, society in general and the metropolitan centers where the disease is concentrated, data on the costs of treating AIDS patients are very scarce The most frequently cited estimate, by Dr Ann Hardy of the Centers for Disease Control (CDC), put the lifetime direct medical care costs of an AIDS patient at $147,000 This estimate was made in early 1985 and admittedly based on very fragmentary data

To fill some of the data gap in this area, my staff and I began in early 1985 to study the costs of treating AIDS patients in San Francisco San Francisco has the second largest number of AIDS cases, after New York, totalling 1,990 through March 24, 1986, or 10.7% of the 18,576 reported AIDS cases in the United States We have completed a retrospective study of the costs of treating AIDS patients at San Francisco General Hospital (SFGH) in 1984 SFGH is the city and county hospital and in 1984 treated about one-half of all AIDS patients in San Francisco In addition, we have just begun a prospective study of the costs of treating AIDS patients in San Francisco in which we will include not only patients treated at SFGH but also by community physicians and by physicians at the Kaiser Permanente Health plan who currently treat about 12% of all San Francisco AIDS patients. These two studies have been supported by grants from the University of California Universitywide Task Force on AIDS. Finally, one of my colleagues at the University of California in San Francisco, Mrs. Dorothy Rice, the former Director of the National Center for Health Statistics, and I have just completed estimates of the nationwide direct and indirect costs of the AIDS epidemic in 1985, 1986 and 1990 for the Centers for Disease Control (CDC) which supplied us with estimates of the number of AIDS cases in these three years.

Our 1984 San Francisco study yielded three sets of data: (1) average charges per AIDS admission, by specific diagnosis; (2) average inpatient and outpatient charges of AIDS patients who received all their inpatient and outpatient care at SFGH in 1984; and (3) lifetime inpatient charges of AIDS patients who died in 1984 and had received all their inpatient care at SFGH.

To summarize our data very briefly, the average charge per AIDS admission, including inpatient professional charges, was $9,024; charges ranged from $2,440 for admissions for diseases of the blood to $14,120 for admissions for pneumocystis carinii pneumonia. Average inpatient and outpatient charges for AIDS patients who had received all their inpatient and outpatient care at SFGH in 1984 were $15,993. They were highest for patients who died in 1984, $23,425, although on the average these patients had expenses for only 6 months of 1984. They were lowest for patients who lived all 12 months, $7,026, who were mainly patients with Kaposi's sarcoma who can be treated largely on an outpatient basis. In between were the expenses of patients who were newly diagnosed in 1984, whose average expenses were $12,040 in the somewhat more than four months they incurred expenses. Finally, lifetime inpatient charges of AIDS patients who died in 1984 were $27,571 spread over 224 days, their average survival time from diagnosis to death.

To the best of my knowledge, no other systematic studies of the costs of treating AIDS patients are available at this time, although I know of several that are currently being conducted. However, I have been able to secure unpublished data from a number of state and city health departments, a few hospital organizations, and a number of hospitals on average length of hospital stay of AIDS patients and average charges or costs per AIDS patient day. These data suggest that costs are lower in San Francisco, mainly because of a substantially lower length of hospital stay. While the length of hospital stay per AIDS admission is between 12 and 13 days in San Francisco, it ranges from 12 to 72 days in other locations, with a clustering around 15 to 25 days. The range of average charges per AIDS patient day is smaller, from $470 to about $1,000, with a clustering around $750 to $950.

The main reason for the shorter length of hospital stay in San Francisco is the well-organized gay community which through a variety of community organizations has enabled AIDS patients to be discharged sooner than in other areas and be treated on an ambulatory basis. There is also a difference in the patient population, San Francisco AIDS patients being predominantly male homosexuals, with only 15% being IV drug abusers compared to New York's 30%. It is likely, though the evidence is not entirely unanimous, that IV drug abusers have longer hospital stays because they have few places to which they can be discharged.

On the basis of the data from San Francisco and from other sources, I made estimates of the direct medical care costs of AIDS patients in the United States for 1985, 1986 and 1990 for CDC. For 1985, my estimates range from $314 million to $945 million, with a medium estimate (which I regard as the most likely) of $517 million. For 1986, CDC gave us a low and high estimate of the number of AIDS cases. My estimates using the low CDC prevalence estimate range from $527 million to $1.6 billion, with a medium estimate of $870 million. Using the higher CDC estimate, my estimates range from $623 million to $1.9 billion, with a medium estimate of $1 billion. These estimates are in constant 1984 dollars. The high and low CDC prevalence estimates for 1990 are so different that I have little faith in the usefulness of my estimates for that year.

To give these estimates some perspective, they must be set within the framework of other health care expenditures. As a percentage of total personal health care expenditures, they are a fraction of 1% (0.1% to 0.9% for the low and high estimates, respectively). They are also considerably less than the direct medical care expenditures for other diseases. In 1981, for example, Medicare reimbursements for patients with end-stage renal disease amounted to $1.5 billion. In 1980, it is estimated that we spent $6.4 billion for all infectious and parasitic diseases, $19.6 billion for neoplasms, and $50.7 billion for diseases of the circulatory system (in 1984 dollars). This is not to belittle the costs of the AIDS epidemic. There is no doubt that it imposes a heavy strain on the medical resources of the metropolitan areas where the disease is concentrated, especially on their public hospitals. This makes it essential to devise alternatives to inpatient care to the extent this is medically feasible.

To sum up, while AIDS clearly imposes serious financial burdens, I think some of the medical care cost estimates publicized to date, especially the much-quoted $147,000 lifetime cost estimate of Dr. Hardy of the CDC, are much too high. Evaluating all the data I have been able to examine, I would say lifetime medical care costs of an AIDS patient are at most $90,000 to $100,000, and they may well be closer to $60,000 to $70,000. In addition, there is some evidence that costs have been coming down, mainly because the average length of hospital stay appears to have been declining. There is also some evidence that the use of intensive care units (ICUs) has been declining because it was found that in many instances the use of ICUs prolonged dying rather than living. Finally, the example of San Francisco shows that costs can be lowered substantially given adequate community facilities for outpatient care. Thus the AIDS medical care cost situation is not quite as devastating as it has been pictured.

It must be remembered, however, that the direct medical care costs of AIDS are only part of the costs of the epidemic. In addition, there are non-personal health expenses for research, blood screening, and health education, and there are the indirect costs resulting from loss of production due to morbidity and premature mortality. Because most of the AIDS victims are young persons in their most productive years of life, these indirect costs amount to several times the direct medical care costs.

QUESTIONS FROM SENATOR HATCH

QUESTIONS FOR DR. SCITOVSKY

1) Have you estimated or are you aware of estimates of the indirect costs of AIDS resulting from loss of victims from the work force due to morbidity and premature mortality?

2) Can you attribute the difference in cost of AIDS care between San Francisco and New York, for example, entirely to shorter length of hospital stay?

3) If not, what other factors besides shorter length of hospital stay seem to be involved in the economic success of San Francisco's programs?

4) Do you have any ideas from your study as to how the cost of care of AIDS patients could be reduced even further? Without affecting qualtiy of care of course.

5) You stated that progress is being made in San Francisco to treat AIDS patients on an ambulatory basis. Who is paying for these services and what type of facilities are providing them.

6) Do you believe there is under reporting of AIDS, at least in its early stages?

7) If so by how much and what impact would this have on your economic estimates?

RESPONSES TO QUESTIONS FROM SENATOR HATCH

1. Mrs. Dorothy Rice of the University of California, San Francisco, made estimates of the indirect costs of AIDS as part of our joint report to the Centers for Disease Control. A copy of this report, as requested by Senator Kennedy, is enclosed.

2. and 3. We cannot attribute differences in AIDS costs between San Francisco and other communities solely to shorter hospital stays. There are also probably differences in case mix (admissions for pneumocystis pneumonia vs. Kaposi's sarcoma, for example for which average charges are quite different) and differences in the average number of admissions per person. However, data we collected for the enclosed CDC study, limited as they are, show a clustering of average daily hospital charges from $740 to $940, so one might assume that daily intensity of care was similar nationwide. Therefore the greatest variable affecting total costs would be number of days in the hospital. Because outpatient facilities - nursing home, hospice, home health care and living quarters for homeless victims are available in San Francisco much more than they are elsewhere, hospital stays can be shortened or avoided in some instances.

4. Because we are not physicians, we do not feel qualified to make any specific recommendations for changing medical care to reduce costs without affecting quality of care. But there must be some changes which could be made. As an example, at San Francisco General Hospital in 1984, a number of admissions for one or two days occurred

for patients who required blood transfusions because of severe anemia. In 1985, a facility was set up to provide these transfusions on an outpatient basis.

5. This reference was to home health care, nursing home and hospice care as well as to the change to outpatient blood transfusions mentioned above. These services are paid for by a variety of payors...private insurance and MediCal, when the individual has such coverage, and to the extent to which they cover a particular service; and by money provided towards operating expenses of the various AIDS service groups by the City of San Francisco, as well as by private donations. There are also volunteer services; persons who, after a short training period, provide non-medical services to home-based AIDS patients such as grocery shopping, food preparation, transportation and companionship.

6. and 7. We have no idea if there is under reporting of AIDS. We would suspect there may be some but it probably does not affect our estimates of AIDS costs much. What is a much larger problem is the number of persons with ARC. Our estimates do not include ARC cases nor costs of treatment for ARC for those persons who go on to develop AIDS. Dr. Curran at the CDC estimated last summer that there are at least 5 to 10 cases of ARC for each case of AIDS reported. ARC patients get sick, are hospitalized and some patients have died from ARC. No one has estimated these costs; no firm definitiion of ARC has been established although a group of physicians in San Francisco, led by Dr. Donald Abrams of San Francisco General Hospital, are currently trying to create a working definition. Once one is agreed on, cost estimates should be made.

Senator Kennedy's
QUESTIONS FOR SCITOVSKY

1. You noted that the total cost for neoplasms was 19.6 billion, much greater than that for AIDS. But there are over 10 million people with cancer, and only 19,000 with AIDS. So in fact, the per patient cost of AIDS is extremely high. Wouldn't you agree?

2. Why do you think Dr. Hardy's estimates are so far off the mark?

3. Do you have figures to share with us about indirect costs?

4. ~~Haven't you prepared a report with Dorothy Rice for the CDC on Direct and Indirect Cost of AIDS.~~

   Could you submit for the record a copy of that report? I would like to request a copy of the report done by yourself and Dorothy Rice for the CDC on the direct and indirect cost of AIDS?

5. In your statement, you offered us some perspective by suggesting the total health expenditures for AIDS in 1986 will be $1 billion, which is much less than other total expenditures. But in fact the cost for end stage renal disease back in 1981 was about the same 1.5 billion. Don't you think that is still a considerable sum?

6. Have you done any analysis on the actual "health" costs of asymptomatic carriers detected by mass screening? In other words, does finding out that someone is AIDS antibody positive, but asymptomatic lead to further tests (chest X-ray, CAT SCAN increased number of visits, etc.)

7. Many of your figures are based on SFGH which as you mentioned is in a unique setting because of community organizations and the hospitals' city/county support? You did not however mention the fact that SFGH uses a special AIDS ward for its patients. What effect does an AIDS ward have on AIDS cost?

8. Are there differences in cost between San Francisco and other cities such as New York City? What do you think the reasons for this are?

RESPONSES TO QUESTIONS FROM SENATOR KENNEDY

1. We would agree that the costs on a per person basis for persons with AIDS, per year, are extremely high in comparison with equivalent costs for cancer. If one wants to compare per person lifetime costs, on average a cancer patient probably lives a lot longer than an AIDS patient and so can incur cancer-related expenses for years, whereas the AIDS patients we studied for 1984 lived an average of only 224 days from diagnosis to death. We tried unsucessfully to find equivalent lifetime cancer (or any other disease) costs for this comparison and so presented yearly data unrelated to a per person cost.

2. Hardy's estimates were based on a small number of cases and at a point early in the AIDS epidemic. Our estimate is based on a larger number of cases, nationwide, (but still a small number) and has the added advantage of noting decreasing costs over time. (As we have noted, lengths of admissions have been dropping around the country.) Dr. Hardy did qualify her data, as we do too. It is very unfortunate that the media, when reporting her findings, did not make clear the iffy-ness of the estimates and that insurance companies snatched the figure and made policy based on it that immediately affected the quality of life of persons with AIDS.

3. and 4. Enclosed is a copy of the CDC report you requested which includes data regarding indirect costs.

5. Yes. We only offered these figures as comparison, to provide some perspective - not to belittle the costs of AIDS which are also very high.

6. We have not done any analysis of "health" costs of screening. We agree that there are very probably increased visits and testing done for symptomless persons with positive antibody tests. Also not included in any estimates we have done are costs for persons with ARC. These can be considerable; see comments to questions 6. and 7., asked by Senator Hatch.

7. We don't know what difference the special AIDS ward has on costs at San Francisco General Hospital. For our 1984 retrospective study, we actually identified admissions to the AIDS ward versus those to other wards (as well as some which used both types of wards during an admission) but we did not analyze this data for several reasons.

First, we were using charge data, from bills, not cost data. San Francisco General Hospital charges the same for a room on the AIDS ward as for any other hospital room. In addition, the doctors at San Francisco General Hospital thought that the course of treatment for any patient would be the same no matter what room he was in, as far as numbers and types of services provided were concerned. In otherwords, what was available on the AIDS ward which was not necessarily available in other rooms was not something measureable by the data we collected. As a result, comparing charges between the two types of wards was low on our list of priorities and we did not come to it before we ran out of time and funds for the project.

8. Yes, there are differences in costs between San Francisco and other cities. This may be related to the number and types of non-hospital services available as well as non-medical support groups, as well as to the variation in risk-group distribution and admission diagnoses between San Francisco and other cities. For example, it is hypothesized that IV-drug users are hospitalized longer, have more serious and more frequent opportunistic infections requiring admission than do non-IV drug users. This is yet to be documented. See pages II7-8 of the enclosed report and Table 6, pages II20-24.

(EDITOR'S NOTE: In the interest of economy, and due to the voluminous content of the report referred to, only its Summary and those pages specifically referred to are included in the printed record of this hearing. It is suggested that parties desiring copies of the complete report should contact the Center for Disease Control.)

Excerpts from:

FINAL REPORT

ESTIMATING THE DIRECT AND INDIRECT ECONOMIC COSTS OF ACQUIRED IMMUNE DEFICIENCY SYNDROME, 1985, 1986, and 1990

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Prepared for
The Centers for Disease Control
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This report was funded by the Centers for Disease Control (CDC)under Task Order 282-85-0061 #2. The authors prepared the estimates of the direct and indirect economic costs of AIDS based on prevalence estimates provided by CDC of the course of the AIDS epidemic in 1985, 1986 and 1990, and the distribution of the cases by diagnosis and by patient group (alive all 12 months but diagnosed prior to year, died during year, and diagnosed during year and alive at the end of the year). The cost estimates, interpretations and conclusions, however, are those of the authors, and should not be attributed to CDC.

The estimates of the direct medical care costs of AIDS were prepared by Anne Scitovsky with the assistance of Mary Cline, Palo Alto Medical Foundation. The estimates of non-personal costs were prepared by Dorothy Rice and Bruce Kieler with the advice of Jonathan Showstack, University of California, San Francisco. The estimates of indirect costs were prepared by Dorothy Rice with the assistance of Arden Wick and Jonathan Showstack, University of California, San Francisco. The authors are grateful to Norman Axnick, Director, Office of Program Planning and Evaluation, Centers for Disease Control, for his advice and support throughout the project.

CHAPTER I

SUMMARY

INTRODUCTION

Acquired immune deficiency syndrome (AIDS) made its first appearance in the United States in 1979. At first a rare occurrence, the condition has assumed alarming proportions. Since reporting began in 1981, more than 18,000 cases of AIDS have been reported to the federal Centers for Disease Control (CDC) with 9,591 deaths as of March 10, 1986.

Aids is a devastating condition, depriving individuals of the ability to combat disease. Persons with AIDS, chiefly younger people from 20 to 40 years of age, develop a variety of opportunistic infections. Many also develop AIDS-related malignancies, including a rare neoplasm, Kaposi's sarcoma. Death usually occurs within two years of diagnosis. Because AIDS affects a relatively young population, its economic impact is high. This report estimates the direct and indirect costs of AIDS in the United States for the years 1984, 1985, 1986, and 1990.

The estimates are based on prevalence estimates provided by CDC. At our request CDC classified by age and sex all AIDS cases alive at any time in 1984 into the following three patient groups:

1. Those diagnosed in a prior year who lived all 12 months;
2. those who died in the year; and
3. those who were newly diagnosed and did not die.

Within each of the three patient groups, the cases were distributed in the following diagnostic categories: Pneumocystis Carinii Pneumonia (PCP), other infectious diseases, Kaposi's Sarcoma (KS), neoplasms, and other conditions. These detailed distributions of AIDS cases were provided by CDC for 1984. This year was selected because it was the first year that health departments in the United States confirmed all cases using the strict definition of AIDS. In addition, 1984 data are complete and there are no reporting lags as there would have been had we used 1985 data.

CDC estimated the total number of cases in each of the other years (1985, 1986, and 1990) and assumed that the distribution by age and sex and between these patient groups and diagnostic groups within each patient group remained the same over time.

The following costs were estimated:

1. Direct costs
    a. Personal medical care costs
        * Hospital services
        * Physician inpatient and outpatient services
        * Outpatient ancillary services
        * Nursing home, hospice, and home health care
    b. Non-personal costs
        * Research
        * Blood screening and testing
        * Replacement of blood
        * Health education
        * Prevention, control and support services
2. Indirect Costs
    a. Morbidity costs - value of productivity losses due to illness and disability
    b. Mortality costs - present value of future earnings lost for those who died prematurely as a result of AIDS.

No attempt was made to estimate the psychological costs due to AIDS even though it is recognized that these are real and great for the AIDS victims and their families. All estimates are in 1984 constant dollars unless otherwise noted.

The specific methodologies for estimating these costs are described in detail in the body of the report; only the findings are summarized here.

FINDINGS

Estimates for each year are shown in summary Table 1, including low, medium and high estimates based on alternative assumptions of medical care and nonpersonal costs and two discount rates (4 and 6 percents) for mortality costs that are described in detail in each section of the report. Total economic costs range from a low of $3.3 billion to $4.5 billion in 1985. These cost estimates assume that there were 15,400 AIDS cases in that year, including the three patient groups: those diagnosed in a prior year who lived all 12 months, those died in the year, and those who were newly diagnosed and were alive at the end of the year. This prevalence approach differs substantially from the lifetime approach used by other analysts.

AIDS has been spreading at significantly differing rates throughout the nation. In 1986, CDC estimated a low and high prevalence of 25,900 and 30,600 AIDS cases, respectively. Total direct and indirect cost estimates for the low prevalence figure ranges from $5.6 billion to $7.6 billion; for the high prevalence figure, the range is $6.5 billion to $8.9 billion. For 1990, the low prevalence figure is identical to the 1985 figure of 15,400 cases. This low figure assumes that an effective vaccine will be available and the AIDS virus, HTLV-III/LAV, will be under control. The high prevalence figure of 76,500 cases is about five times that of 1985 and the range of cost estimates in 1984 constant dollars is also about five times the 1985 figures -- $15.7 billion to $21.9 billion.

We believe that the medium estimates shown in summary table 2 may be closest to the actual costs. The following discussion therefore focuses on medium estimates shown in Table 2. Based on a prevalence of 15,400 AIDS cases in 1985, the total economic costs of AIDS amounted to $4.1 billion. Of this total, direct costs comprised 20.3 percent, and indirect costs 79.7 percent.

The direct medical care costs comprise three-fifths of the total direct costs; the remaining two-fifths are the non-personal costs.

The indirect losses incurred by AIDS patients are significantly larger than the medical care and nonpersonal costs because AIDS affects many persons in their most productive period of their lives. Of the total estimated indirect costs of $3.3 billion in 1985, 6 percent represent morbidity losses, the estimated value of losses in productivity resulting from illness and disability for the 15,400 AIDS cases. The remaining 94 percent of the indirect costs are the estimated value of productivity losses for 5,500 persons who died prematurely in 1985 from AIDS.

With the projected increase in prevalence, the total economic costs of AIDS will increase commensurately. The number of AIDS cases is estimated to rise from 15,400 cases in 1985 to a high of 76,500 cases in 1990; the total direct and indirect costs are estimated to increase from $4.1 billion in 1985 to $19.6 billion in 1990. The distribution of costs by type of cost remains fairly constant as shown in summary Table 2.

Summary Table 3 shows the number of deaths from AIDS, person years lost, and mortality costs by sex. Applying the expected years of life lost by age and sex to the 5,500 deaths in 1985 results in a total of 217,693 person years lost, an average of 40 years lost per death. Taking into account losses of future earnings and an imputed value for housekeeping services by age and sex results in a loss of $3.1 billion to the economy at a 4 percent discount rate for the 5,500 deaths in 1985. For the 5,046 men estimated to have died in 1985, losses are valued at $2.9 billion. Men account for 92 percent of the deaths, 90 percent of the person years lost, and 94 percent of the mortality costs.

The number of deaths are projected to rise from 5,046 in 1985 to a high estimate of 27,200 in 1990; person years lost will rise from 217,693 in 1985 to 1.1 million in 1990; and mortality costs are projected to increase to a high of $15.2 billion in 1990.

ECONOMIC COSTS OF AIDS AND THE TOTAL COST OF ILLNESS

AIDS victims are mainly young adults in the age range of 20-40 years and in their most productive period of life. Nevertheless, it is important to view these total direct and indirect costs as part of the total cost of illness in the nation. Total personal health care expenditures amounted to $387.4 in 1984; the indirect costs of morbidity and mortality for all illness and deaths in the United States is estimated at $304.7 billion in 1984; and the total direct and indirect costs amount to $692.1 billion. Our estimates for 1984 of the direct and indirect costs of AIDS total $1.9 billion, a fraction of 1 percent of the total economic costs for all diseases. If the AIDS virus continues to spread and kills significantly more persons in 1990, as projected in the high estimates, their economic costs would comprise a larger share of the nation's total cost of illness, but still less that 1 percent of the total.

LIMITATIONS OF THE ESTIMATES

It must be stressed that our estimates have very serious limitations:

1. The wide differences in the prevalence estimates provided by CDC underscore the large differences in costs under alternative assumptions regarding the future course of the disease.

2. The assumption that the distribution is constant over time between the three patient groups and the various diagnostic groups is problematical.

3. The assumption that medical treatment, the organization and delivery of support services and other nonpersonal services will remain unchanged over time is unrealistic.

* * * * * * *

Average charge per hospital day	$950
Average outpatient charge per case	$2,000
Very high	
Average number of hospital admissions per case	2.5
Average number of hospital days per admission	25
Average charge per hospital day	$950
Average outpatient charge per case	$2,000

Table 5 shows the results of these estimates. For 1984, our estimates range from a low of $155.6 million to a high of $469.2 million. For 1985, they range from $313.5 million to $945.2 million; for 1986, they range from $527.2 million to $1.6 billion assuming the low CDC prevalence estimate and from $622.8 million to $1.9 billion assuming the high CDC estimate; finally for 1990 they range from $313.5 million to $945.2 million and from $1.6 billion to $4.7 billion using the low and high CDC prevalence estimates, respectively.

The low estimates are based on the data derived from our SFGH study, shown in Table 4, except that we have increased average outpatient charges to $4,000. We made this adjustment to take account of non-hospital outpatient charges (mainly home health and hospice care) which we estimated on the basis of expenditures of one of the San Francisco voluntary agencies providing home health and hospice care to AIDS patients.

We regard these low estimates as the very lowest possible estimates because they are derived from data from SFGH. Data from other areas suggest that costs of treating AIDS patients in San Francisco are considerably lower than elsewhere, primarily because of a very much shorter average length of hospital stay. There are several reasons for this shorter length of hospitalization. For one thing, the vast majority of San Francisco AIDS cases are male homosexuals and only about 15% are IV drug users who in New York, for example, constitute

35% of all AIDS cases.[2] It is possible that IV drug users have few sources of social support and hence stay in the hospital longer because there is no alternative place for them to go. The evidence for this hypothesis, however, is not conclusive. For example, a study by the State of New York Department of Health found no significant differences in average length of stay and average charge per hospital day between IV drug users and all other AIDS patients.[3] A more important reason for the lower hospital use by AIDS patients in San Francisco is the well-organized gay community which helps patients to leave the hospital sooner and receive care on an outpatient basis. Thus our low estimates can be regarded as estimates of the national direct costs of AIDS patients if the special conditions existing in San Francisco prevailed nationwide.

For the other estimates, we have made use of data from our review of all other sources which we were able to obtain. These are summarized in Table 6 and are reviewed briefly below.

Data on average number of admissions per case. Data on this variable are extremely scarce. A study conducted in Massachusetts, very similar to our SFGH study of AIDS patients who received all their inpatient and outpatient care at SFGH in 1984, evaluated the utilization and costs of medical services of 45 AIDS patients over a 12 month period (Table 6, item 18). This study showed 1.6 hospitalizations per patient during this period, very close to our 1.7 for the United States, based on our SFGH data. A few other estimates, also covering patients over the course of a year but for varying lengths of time, also suggests that 1.7 admissions is a reasonable figure to assume (Table 6, items 3, 7, 13). McHolland and Weller estimated that an AIDS patient in California had a hospital episode every 2.8 months over the course of his life, which averaged 18 months; this would mean 4.3 hospital episodes over a 12-month period (Table 6, item 1). Our estimate of 1.7 hospitalizations per case over the course of a year translates into 3.2 admissions per personyear. In the absence of any other data, we have used 1.7 admissions per case in all estimates except the highest, where we increased ***

* * * * * * *

TABLE 6

Data on average length of hospital stay, average charge per hospital day, and average number of admissions of AIDS patients

Source	Average length of hospital stay	Average charge per hospital day ($)		Average number of admissions*
California				
1. McHolland, G. and Weller, W. Summary Report on California AIDS victims: Quantitative Analysis. California Department of Health Services, October 28, 1986. 415 MediCal AIDS cases (1983-85).		MediCal	Commercial	
California	14.0	606	892	6.4 per patient)
Los Angeles County	17.9	686	1,038	5.6 per patient) per 18
San Francisco	12.1	552	735	6.7 per patient) month
Other California Counties	14.2	598	991	6.7 per patient) period
2. West Bay Hospital Conference, San Mateo, California. AIDS Inpatient Hospital Utilization, San Francisco, January-June 1985 (826 discharges).	12.0		-	-
3. West Bay Hospital Conference, San Mateo, California. AIDS Inpatient Hospital Utilization, West Bay and San Francisco Hospitals, 1984. October, 1985				
1984 (1,134 discharges-665 cases)	12.3		918	1.7 per patient
1983 (230 discharges)	13.9			
1982 (19 discharges)	18.2		-	-
4. West Bay Hospital Conference, San Mateo, California. AIDS Inpatient Hospital Utilization, West Bay and San Francisco, 1982-83. June 1985 (101 cases)	13		876	-

TABLE 6 (contd)

Source	Average length of hospital stay	Average charge per hospital day ($)	Average number of admissions*
5. Hospital Council of Southern California, Los Angeles, California. AIDS Status Report, Hospital Services in Southern California, October, 1985. (976 hospitalizations-110 hospitals reporting on most recent 12 month period. 48 hospitals provided information on charges.)	17.3	963	-
New York			
6. State of New York, Department of Health, Albany, New York. AIDS reports from New York City. Memorandum to Steve Anderman, December 10, 1985. (1,573 admissions, 1984)	18.2	575	-
No ICU use	17.2	518	-
ICU use (only 8.4% had ICU use)	29.1	1,000	-
Drug cases	17.4	587	-
Non-drug cases	18	573	-
7. Passman, Leigh J. AIDS Inpatients: Case Mix and Cost Variation. (Unpublished) (116 cases, NY University Medical Center, 1983)	19.5	-	1.6 per patient
8. Leicht, Daniel, M.D. New York City Health & Hospitals Corporation, New York, New York. Statement before the Labor, Health & Human Services, Education & Related Agencies Subcommittee of the Senate Appropriations Committee, September 26, 1985		749-850	-

TABLE 6 (Contd)

Source	Average length of hospital stay	Average charge per hospital day ($)	Average number of admissions*
9. Spencer, David J., M.D. and Botnick, Victor E. Report to the Mayor, New York City's response to the AIDS Crisis, December, 1985. (HCC hospitals, mid-1985)	25.4	800	-
10. Data from Daniel Fox, New York State Center for Assessing Health Services, State University of NY at Stony Brook, New York. (23 cases, University Hospital, Stony Brook, New York, 1984)	25	940	-
11. Belmont, Mary F. St. Luke's-Roosevelt Hospital Center Study, Resource Utilization by AIDS Patients in the Acute Care Hospital, December, 1985. (152 cases, 1-84/4-85)	22	-	2 per patient over an unspecified period
12. Draft of table prepared by the New York State Department of Health, Office of Health Systems Management, Albany New York. (1981-1984, does not include diagnosis of KS)			
New York State (3,158 cases)	27.0	-	-
New York City (2,869 cases)	26.5	-	-
Florida			
13. Data from Susan P. Reynolds University of Miami/Jackson Memorial Medical Center, Miami, Florida	21	858	3.2 per patient per two year period

TABLE 6 (Contd)

Source	Average length of hospital stay	Average charge per hospital day ($)	Average number of admissions*
Michigan			
14. Preliminary Report-Michigan Medicaid Expenditures Related to AIDS. Data from James F. Groen, Department of Social Services, State of Michigan, Lansing, Michigan. (10 cases, 1981-84)	20.1	805 (572 Medicaid)	4.2 per patient over an average of 22.6 months [2.3 peryear (my estimate based on these data)]
Minnesota			
15. Data from Jim Shultz, Minnesota Department of Health, Minneapolis, Minnesota. (24 cases, University of Minnesota Hospital, 1-81/12-85)	12.3	917	3.4 per patient over an unspecified period
New Jersey			
16. Baxter, Robert C. and Ksell, Toni E. Needs Assessment, Acquired Immune Deficiency Syndrome, April, 1985. New Jersey State Department of Health, Division of Epidemiology, AIDS Activity, Trenton, New Jersey. (46 cases)	52	-	3 per patient over an unspecified period
Texas			
17. Data from Dorothy Gibson Texas Department of Health, Austin, Texas from Survey of Hospital Cost for AIDS Patients, State of Texas, January, 1985. (5 cases, Houston)	72.2	471	-

TABLE 6 (Contd)

Source	Average length of hospital stay	Average charge per hospital day ($)	Average number of admissions*
Massachusetts			
18. Seage, George R., III. Landers, Stewart; Barry, M. Anita; et al. Medical Cost of Patients with Acquired Immunodeficiency Syndrome (AIDS) & AIDS Related Complex (ARC) (Draft), Department of Community Health, Boston Department of Health & Hospitals, Epidemiology and Statistics Section, Boston University School of Public Health, March 1, 1986. (45 cases, New England Deaconess Hospital, Boston, 3-84/2-85).	21.3	808 (687 cost)	1.6 per patient 3.3 per patient per year
Other			
19. Data from Norman W. Axnick, Centers for Disease Control, Atlanta, Georgia, February 27, 1986			
(20 cases, Chicago, IL)	18.8	-	
(20 cases, Newark, NJ)	20.5	-	
(18 cases, Philadelphia, PA)	29.7	-	
(20 cases, Houston, TX)	15.0	-	-
(20 cases, Washington, DC)	16.0	-	-

* Number of admissions per patient is the number of admissions over the course of the year divided by the total number of patients alive at any time during the year. Number of admissions per patient per year is the total number of admissions divided by the number of months the patients were covered by a study times twelve. If the time during which patients were included in a study was not specified, this is indicated in the table.

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The CHAIRMAN. Ms. Lautzenheiser, unfortunately I have very little time left. You have an extensive statement, and I am going to put it in the record. If you could just summarize in a few minutes, I would appreciate it.

Ms. LAUTZENHEISER. I will do that. Thank you.

Good afternoon, Mr. Chairman. My name is Barbara Lautzenheiser. I am a fellow of the Society of Actuaries; a past president of that international professional organization and a former president and COO of three insurance companies, and I am here today on behalf of the Health Insurance Association of America, a trade association representing 335 companies, which underwrite approximately 85 percent of the private health insurance currently sold in the United States.

The health insurance industry is concerned about this issue, just as this committee is, and we appreciate the opportunity to be here today.

The AIDS epidemic is tragic, mostly because of its impact on people, as you indicated, and the tragic consequences to them, but it also presents a global public policy challenge, with many people—governments, communities, industry, scientists employers and insurers—joining to mobilize against it.

Today we have heard from the Nation's most senior public health official and in broad-brush strokes, Dr. MacDonald has painted a rather grim picture. But just as Congress and the executive branch have recognized the need for swift action, the insurance industry has also brought substantial resources to deal with this public health issue.

The HIAA and the American Council of Life Insurance recently announced a joint contribution of $1.16 million to fund public education and medical research on AIDS; $900,000 of this is going to the Red Cross AIDS Public Education Program referred to earlier today; $100,000 to the American Foundation for AIDS Research, and $160,000 for joint research by the Sloane-Kettering Institute in New York and the University of Alabama in Tuscaloosa, on the neurological implications of AIDS.

Also, the insurance industry has begun a massive major public education campaign, through our member insurance companies, to encourage dissemination of information to employees and policyholders.

Transamerica Occidental Life Insurance Co., the company I represent, also worked closely with the AIDS project in Los Angeles to produce a video presentation entitled, "Fight the Fear with Facts." We will send each of the committee members a packet of the information being sent to member companies and we will send the committee a copy of the videotape as well.

The CHAIRMAN. We would appreciate that.

Many of our member companies are also planning independent contributions in medical research and public education, as well as developing case management programs, for example, to identify when intensive care is and is not needed, and in order to identify the best facilities for people, as well as exploring expansion of the home health care benefits to better meet the needs of AIDS patients and to promote cost containment.

Although insurance companies are accustomed to taking risks, they are however not able to take chances, and we have been faced with large uncertainties posed by this AIDS crisis. At the top of the list of uncertainties is the number of ever-expanding people who are infected with the AIDS causing virus. Experts originally estimated 400,000 persons. Now, some of those estimates go up to 1 or 2 million persons. CDC predicted 14,000 to 18,000 new cases this year, or almost a doubling of the present 19,000-plus cases. I was glad to hear earlier today that that doubling seems to have slowed up and appears to be happening on a 13 to 14 month basis rather than on a yearly basis now.

However, Dr. MacDonald earlier today said 85 percent of these people would possibly die within the next 3 years. Unfortunately, some of the people who have the virus do not feel unhealthy; they appear to be healthy, and they may be spreading the virus. That is our major concern.

It appears now that 5 to 19 percent of those infected with the virus develop AIDS within 2 to 5 years, and some of those estimates have been raised to 33⅓ percent. Also, there is the possibility now, as Dr. James Curran of the CDC has been quoted as saying, that "heterosexual transmission should be assumed." That makes the statistics even worse.

We are glad to hear also that the estimates of hospital costs for each AIDS victim may have been decreased from $140,000. We are hoping that those statistics prove out.

Whatever the AIDS health care costs are today, unfortunately, we fear they will rise in the future. There are over 160 million Americans covered by health insurance in the United States. And I would like to emphasize, we will pay all AIDS-related claims for persons currently covered under the terms of our existing contracts, just as we pay for any other condition.

So, there is a profound impact already on the health insurance industry, because we have already had unexpected high costs and anticipate more. But, repeating, we will pay all those claims for persons covered under current contracts.

It is clear, however, that the risks undertaken by the insurers can only properly represent fairness and equity for all of our premium-paying policyholders if we are able to have good underwriting practices and continue to do the testing which has been prohibited in two States already. It is our hope that through public education and in maintaining our prompt and fair claims handling, that our industry will be a part of the solution but not the sole solution to a potential national disaster.

The CHAIRMAN. Ms. Lautzenheiser, let me stop you at that point and put the rest of your statement in the record.

Thank you very much.

[The prepared statement submitted by Ms. Lautzenheiser and responses to questions submitted by Senators Hatch and Kennedy follow:]

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1850 K Street, N.W.
Washington, D.C. 20006

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FOR IMMEDIATE RELEASE

HEALTH INSURANCE INDUSTRY URGES PUBLIC/PRIVATE PARTNERSHIP IN SOLVING AIDS CRISIS

Washington, D.C., April 16 -- A spokeswoman for the health insurance industry urged Congress today to work in partnership with health insurers to achieve a solution to the AIDS epidemic.

"The AIDS crisis presents a public policy challenge perhaps unparalleled in this century," Barbara Lautzenheiser, FSA, MAAA, EA, told the Senate Labor and Human Resources Committee. "The epidemic is tragic, for the traumatic consequences it imposes on individuals and their families."

Testifying on behalf of the Health Insurance Association of America (HIAA), Ms. Lautzenheiser stressed the industry's commitment to a resolution of the AIDS crisis. She noted that the HIAA and the American Council of Life Insurance have contributed $1.16 million to fund AIDS-related education and research projects.

"Efforts expended by the insurance industry in regard to the AIDS crisis illustrate our desire to work together with public and private forces to deal effectively with what has become a national crisis," Ms. Lautzenheiser said.

She told the committee that AIDS poses many uncertainties for the industry never faced with any other catastrophic disease. In addition to the present 19,000 cases of AIDS, another one to two million people are infected with the AIDS-causing HTLV-III virus. Most of these people, Ms. Lautzenheiser explained, appear to be healthy and are unaware that they could be spreading the virus.

Because of these uncertainties, she added, the insurance industry must use all pertinent medical information to assess the level of risk that an applicant represents, including results of AIDS antibody tests. She maintained that the AIDS antibody test is a "reliable tool" on which to base the assessment of risk.

Pointing to legislative trends at the state level that would prohibit insurers from using such tests, Ms. Lautzenheiser warned that such action will lead to "adverse selection," a process that allows high-risk individuals to purchase insurance without paying adequate premiums. This, she said, could lead to low-risk individuals paying higher premiums to subsidize those at higher risk, and could eventually result in health insurance becoming unaffordable.

The HIAA spokeswoman assured the committee that the industry would protect the confidentiality of all AIDS-related information, and expressed support for the model privacy protection act of the National Association of Insurance Commissioners. "The industry's record of confidential treatment of medical data is best illustrated by the fact that we have had no reported instances of litigation against insurers or complaints to state insurance departments arising out of unauthorized disclosure of information."

Ms. Lautzenheiser also expressed industry support for federal legislation that would encourage states to establish qualified risk pools for people considered uninsurable in the individual insurance marketplace. The legislation would set minimum standards for such pools and would require all insurers in a state to share the losses. Nine states currently have some type of pool for high-risk individuals, including AIDS patients, she pointed out. The legislation has the support of 30 national disease-related organizations, including the Acquired Immune Deficiency Foundation.

The HIAA spokeswoman assured the committee that the health insurance industry has acknowledged its responsibility to bear medical costs associated with AIDS for current health insurance policyholders.

"AIDS already has had a profound impact on the health insurance industry," she said. "It is clear, however, that the risks undertaken by health insurers can only properly represent the interests of premium-paying policyholders if our industry is not impeded by prohibitions against time-honored underwriting practices. This epidemic has implications that go beyond our capacity."

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ANSWERS TO SENATOR KENNEDY'S QUESTIONS

FOR

HEALTH INSURANCE ASSOCIATION OF AMERICA

1. Do you consider a positive antibody test as the only criterion of high risk for AIDS?

Elisa and Western Blot tests are the only objective and AIDS-antibody-specific tests for determining who actually is infected with the HTLV-III virus. Since they do measure the presence of antibodies to combat the virus, which is one of the first things to occur when a person is infected with the HTLV-III virus, they are not only objective and specific, but the earliest tests for determining whether the person is at a high risk for AIDS.

Knowing that a person is at a high risk for AIDS as early as possible is important in pricing insurance fairly and equitably. Pricing fairly and equitably means that the price is determined by the insured person's own characteristics - age, sex, occupation, avocation, smoking habits, family history -- and health. Thus, the individual's own expected experience is used. The detection of any life-threatening factor in its earliest stages, or even factors that probably lead to disease, such as smoking, indicates that person's probable experience, that person's predictability, and hence his or her cost of insurance. AIDS antibody tests, like EKG's, help identify in the early stages those who may be high risk for a particular disease, and hence, have a higher cost of insurance.

To do otherwise would allow persons with hidden knowledge of their own conditions to "game" the system, driving up the cost of insurance for others and ultimately threatening the viability of the system.

2. Would development of "insurance pools" at the state level in order to cover individuals and groups of less than 10 solve the insurance industry's problem with respect to AIDS?

Health insurance "risk pools" such as those contemplated by S.2402 would guarantee the availability of comprehensive health insurance to all Americans regardless of the condition of their health, including those with AIDS, and are strongly supported by the HIAA.

QUESTIONS FROM SENATOR HATCH

1. To your knowledge is the insurance industry considering more restrictive underwriting of life or health insurance for persons with lifestyles that would place them at a higher than normal risk for contracting AIDS?

According to Dr. Donald MacDonald, acting Assistant Secretary for the Public Health Service, U.S. Department of Health and Human Services, over 90 percent of the adult AIDS cases have occurred among homosexual or bisexual men and intravenous drug abusers. Of the remaining 10 percent of cases, .9 percent are hemophiliacs, 1.4 are heterosexuals who have had sex either with an AIDS patient or with a person in a high risk group, and 1.9 percent have had a transfusion as their only probable cause of infection. Approximately 2.1 percent of cases are people for whom a risk factor is not apparent, but who were born in another country where heterosexual transmission of infection appears to be more common than it is in the United States. Another 3.3 percent of cases have not had a probable means of infection identified, either because of death, inability to follow-up, or investigation still in progress.

With the percentage of AIDS cases having been so large among the homosexual or bisexual men and intravenous drug abusers group, those groups have been the first to be tested for the HTLV-III antibodies. Some companies, however, have been testing all medically underwritten policies in specific states and other companies have been testing all medically underwritten policies in all states. As the results of these companies' testing across the board are made known, and especially if the disease should spread further into the heterosexual population, it is probable that more and more companies will move to testing all medically underwritten policies.

It should also be noted, that the taking of the AIDS antibody test is not more restrictive underwriting but more specific underwriting. The test separates those who do not have the AIDS antibodies from those that do and hence produces a more accurate determination of those persons who are not infected with the virus. It provides an objective criteria which has nothing to do with lifestyles.

2. Is there likely to be any tighter underwriting of such insurance policies for hemophiliacs, who are at a higher risk of contracting AIDS because of the impurities present in blood transfusions?

Only .9 percent of those who have AIDS are hemophiliacs and only 1.9 percent have had a transfusion as their only probable source of infection. The risk of hemophiliacs becoming infected should also decline with time, because those hemophiliacs who are at a high risk of having been infected, are only those who required repeated infusion of clotting factor concentrates from 1980 to 1984 to control bleeding episodes. The clotting products are synthesized from large numbers of donors. Heat-treating of these products since 1984, is believed to have greatly reduced the risk of such transmission. HTLV-III antibody testing that is now being done by blood banks prior to donation of blood, should also virtually eliminate the risks arising from future infusions of blood products. In the case of hemophiliacs too, AIDS antibody testing is objective, not restrictive, underwriting to determine those who are not at a higher risk of contracting AIDS because of the lack of presence of the AIDS antibodies, rather than putting all those who have received blood transfusions between 1980 and 1984 in a single group.

3. We have been given estimates of the lifetime costs of medical treatment for AIDS patients ranging from $60,000 to $90,000 by Ms. Scitovsky to $147,000 by the Centers for Disease Control. What is your own estimate based on the insurance industry's claims experience?

As the Committee is aware, there seems to be little data reported on the costs of treating AIDS patients. To date, there has been an estimated $1.25 billion of hospital costs incurred by the first 9,000 AIDS victims. Estimates of the cost of hospital care for a single AIDS patient range from $42,000 to $147,000. According to the Centers for Disease Control, this has resulted in average hospital costs of $147,000 for each AIDS victim. This does not reflect the cost of outpatient visits to physicians and clinics. Not only is $147,000 low for health claims, it does not take into consideration disability and death claims, both of which have a significant impact on the insurance industry.

Insurance companies find it very difficult to compile such data, in many instances, an insurance claims examiner can only assume that a case is an AIDS case since the word "AIDS" is generally not mentioned. Even on death certificates, it seems that doctors are reluctant to list AIDS as an underlying cause of death.

Despite these limitations, the Health Insurance Association of America is in the process of surveying its member companies to determine the cost of AIDS related claims. Our AIDS survey will attempt to quantify the impact which AIDS related health, disability and death claims have on the insurance industry. In our continuing efforts to be of assistance, the HIAA would of course be happy to furnish the Subcommittee with our survey results when they are received.

4. How will the cost of treating AIDS affect the pricing of health insurance? That is, will higher risk groups be surcharged or will the costs be borne equally by all policyholders?

The effect on the pricing of health insurance of the cost of treating AIDS will vary as between group coverages and individual coverages.

About 85 percent of the insured population is covered by group health insurance. In group insurance, an individual's evidence of insurability is generally not required. No medical information is collected, including AIDS related information.

Group insurance today is generally either "experience rated" or self-insured. Thus, the cost to the employer is adjusted as the actual claims on the group are experienced. The additional cost of treating AIDS is charged directly back to the employer -- and employees if the contract provides that the employees pay part of the cost.

In contrast, in the area of individual health insurance, an individual's evidence of insurability is generally not only required, but necessary.

Collection of all relevant medical data is mandatory for accurate estimation of the risk. Individual underwriting requires the ability to price insurance fairly, and to price insurance fairly and equitably, the price is determined by charging the person according to his or her own characteristics - age, sex, occupation, avocation, smoking habits, family history -- and health. So that the individual's own expected experience is used for pricing. For those diseases where the additional risk cost can be quantified at a reasonable level, surcharges can be made to the entire group for whom the additional risk is present, hence the costs would be borne equally by all of those with a common risk. This, again, is necessary for fair and equitable pricing on individually underwritten insurance. It is better put by the Supreme Court in Griggs vs Duke Power Company as, "Equality of treatment may be denied as much by requiring apparently identical benefits be provided to persons unequally situated as by requiring different benefits to be provided to persons equally situated." More simply, it's as unfairly discriminatory to treat unequals equally as it is to treat equals unequally.

In some cases, however, the costs cannot be quantified, or if quantifiable they are too large to be a reasonable surcharge. If these costs were to be borne equally by all policyholders, it would not only be discriminatory against persons who were healthy, but it would also be discriminatory against persons with a history of other diseases, such as coronary heart disease, cancer, diabetes, etc., since the insurance companies would be charging these groups more because of the state of their health, but wouldn't be able to do so with persons infected with the AIDS virus. It does not seem reasonable that a person with a history of cancer should subsidize persons more likely to contract AIDS. Thus, higher risk persons - of whatever risk - will be surcharged.

5. Will the same be true for life insurance pricing?

The same is true for life insurance as for health insurance, except the vast majority of life insurance is purchased on an individual rather than on a group basis. In individual life insurance there is also more difficulty in developing a surcharge because of the unlimited amount of benefits on the life insurance contract, and because of the large relativity of the size of the life insurance payment to the premium that is charged per year. The closer the probability of death is to 100 percent, the closer the premium must be to the benefit itself. For example, there is no way the life insurance industry can charge $140 per year to a male aged 30 for a $100,000 one year term policy, if his probability of death is near 100 percent or 10 percent or anything greater than one-tenth of one percent, because that's the probability of death in the next year of a health male aged 30. As in individual health insurance, in individual life insurance to have the costs borne by all policyholders would not only discriminate against healthy people, but would discriminate against people who have cancer, or diabetes, or other life-threatening illnesses.

6. Do most of the health insurance policies now inforce in this country cover the full cost of treatment for persons who are suffering from AIDS?

As previously noted, 85 percent of the health insurance coverage is group coverage. To the best of our knowledge, all group contracts cover the costs of treatment for persons who are suffering from AIDS as they would cover the cost of any other illness.

7. Do you think that these current terms of coverage are likely to change in either direction in the immediate future.

With the rate of spread of the disease slowing from doubling every year to doubling only ever 13 or 14 months, as well as the costs of health insurance for AIDS claims stabilizing or possibly decreasing through the development of case management programs, directing patients to facilities where they can receive quality care at a cost effective manner, or through further expansion of home health care benefits for cost containment, it is hoped that AIDS claims can continue to be covered as any other claim for group health insurance.

8. What about long-term?

Long-term will clearly depend upon the spread of the disease, particularly if it spreads to the heterosexual population. Even if the average claim costs stabilize or decrease, if total health care claim costs continue to rise as a result of AIDS, it could cause changes.

The **Chairman**. I must conclude this hearing. Let me ask one question of you, Dr. Fineberg. This may be a question that is on the minds of everybody who is not as well educated as you and your colleagues on this subject. What consideration is being given today, and what precautions are being taken if the current belief that AIDS is not spread through casual contact is shown to be incorrect?

Dr. **Fineberg**. When we talk about assurances in scientific terms, absolutes are never reached. All the evidence, which includes extensive testing of families living in intimate association with patients who have AIDS, confirms the belief that AIDS is not transmitted in a casual manner.

A disease and a virus have a personality in a sense, metaphorically, like an individual. When you learn and understand the behavior of that virus, you have increasing confidence with each confirmation of your observation that your belief is correct.

I think that it is a virtual certainty with what we know today that AIDS virus is transmitted only in the manners which have been described.

The **Chairman**. You do not see any problem, then, at all?

Dr. **Fineberg**. I personally do not see a real problem at this level of uncertainty.

It is more certain, Senator, I believe, than the risk that any one of us would take of dying from being struck by lightning in the next year.

The **Chairman**. That is very interesting. I think it is good for the public to hear that.

I want to thank all of our witnesses for being here today, and especially this last panel. I think we have had a very good hearing. I think it is just the beginning of hearings we are going to have to hold on this very important public health problem.

It just brings home to me again something that I have been fighting for ever since I have been here, and that is home health care. I believe we have got to wake up in this country and realize the way to save money is not only health promotion and disease prevention—I think that is important—but I think home health care is one way of saving money while at the same time giving the most compassionate service we possibly can. I hope that we can—and I think it will save money in the long run. I have to admit a few years back, the Congressional Budget Office really did us in by estimating that my home health care bill would cost an extra $3 billion. I knew it was wrong, but what can you do when they do something like that to you? We have tried to revamp the legislation, and we have passed a number of pieces of legislation that have augmented home health care, but we have not done enough. As you know, we are doing the pediatric home health care bill this year. We think we will pass it through the Congress, and that it may lay the groundwork to show that over the long run, this is the way, or at least one of the ways, to go.

[Responses to subsequent questions and additional material supplied for the record follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary
for Legislation
Washington, D.C. 20201

Mr. James W. Powell
Editor
Committee on Labor and
Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Powell:

Enclosed are the questions and answers for the record of the April 16 hearing on acquired immune deficiency syndrome. We apologize for the delay in getting these to you. The edited transcript was sent to you earlier. Please call Flo Hassell (245-7450) if you have any questions regarding this material.

Sincerely yours,

Patricia Knight
Deputy Assistant Secretary
for Legislation (Health)

Enclosures

QUESTIONS BY SENATOR HATCH

RESEARCH CONTROVERSY

Question:

There has been considerable newspaper publicity concerning what appears to be a scientific dispute between the American research efforts on AIDS and the French research efforts. From these newspaper articles it appears that at one time there had been some collaboration between the American and the French research communities. That collaboration has apparently deteriorated into patent litigation and scientific controversy. Indeed it would appear that both the American and the French have made significant contributions to the identification and culturing of either the same virus or two viruses that are virtually identifical coming from the same family. I recognize that the litigation would restrain some of your answers to many questions but these questions you can answer.

1) Cannot research be more effectively conducted by collaboration through recognized scientific experts than suffer by the current state of acrimony between the American and French groups?

Response:

While the dispute you mention has received a good deal of media attention, international cooperation among scientists has remained largely unaffected. This is perhaps best exemplified by the fact that several hundred U.S. scientists will be participating in the 1986 International AIDS Conference in Paris, including both Dr. Gallo of the National Cancer Institute and Dr. Montagnier of the Pasteur Institute. In addition, there have been many other similar sessions involving scientists both from the U.S. and France over the past year, and there are many ongoing collaborations between researchers from these countries. Naturally, it would be most desirable to put the dispute behind us, and the U.S. is making every effort to find an acceptable mechanism for doing so. However, in the meantime work goes on unabated in the effort to find an effective treatment and cure for AIDS and to better understand the disease.

2) Is not scientific collaboration among recognized experts a more conducive environment to produce better research progress than scientists acting alone without information about other significant developments?

Response:

We agree totally with the need for scientists to share information concerning scientific developments, and for that reason U.S. researchers are among the major contributors to scientific literature. At the same time it must be recognized that some of these developments are of significant commercial value. Through the patent process we are able to protect any valuable rights and encourage commercial investment in our inventions, while at the same time making the benefits of these discoveries known and available to others.

3) Does not this same concept of collaboration apply to efforts by government funded research in United States together with private sector research particularly in view of the epidemic that we face in the AIDS crisis?

Response:

The answer quite clearly is, yes. And for that reason, while a major effort is being waged against AIDS in Government laboratories, the bulk of Federal AIDS money for research is being expended for the award of grants and contracts to universities and other research centers throughout the United States. This is part of a coordinated effort by all sectors of the research community to understand the disease better and find a vaccine, treatment, and cure.

4) What is being done in such domestic areas?

Response:

Our current efforts to conduct and support AIDS efforts in the U.S. are highlighted in Dr. MacDonald's testimony.

QUESTIONS BY SENATOR HATCH

RESEARCH

1. What are the overall priorities of AIDS research plans of PHS?

Recommendations on overall PHS priorities were developed by the PHS Executive Task Force on AIDS. The basic Prevention and Control Plan as developed by the Task Force has the overall priorities: 1) Implement prevention/control program with current technology, 2) Clarify the epidemiology and natural history of the disease and, 3) Develop effective therapies and a preventive vaccine. Lead agencies/institutes are assigned to each of these priorities. The basic approach is to act now to intervene in the transmission of the AIDS virus even as knowledge is being accumulated and therapeutics and drugs are being developed. Recommending priorities within the overall plan are the responsibilities of the appropriate lead agencies.

2. How are you monitoring outcome of plan and quality of results?

Day-to-day progress and quality of research is monitored by the respective agencies. Overall progress is monitored by the PHS Executive Task Force on AIDS. A formal PHS review of progress in research and prevention and control of AIDS is scheduled for June 4-6, 1986. Based on this review the PHS Prevention and Control Plan will be updated, progress noted, and goals modified accordingly.

3. Is there a time-table for plans?

The overall time-table is as follows: (A) By 1987, reduce increase in transmission of HTLV-III infection. (B) By 1990, reduce increase in the incidence of AIDS and (C) By 2,000, eliminate transmission of HTLV-III infection with a decline in the incidence of AIDS thereafter. Specific time-tables have also been proposed for the development of antiviral drugs and vaccines.

4. How close are we to adhering to the time-tables?

In risk groups such as blood transfusion recipients and hemophiliacs, we are ahead of the time-table, with virus transmissions dramatically reduced. Some progress also seems to have been made in other high risk groups, but a full assessment of the effects will require additional time.

Considerable progress has been made on research and development of therapeutics and vaccines. Antiviral drugs are now under clinical evaluation and experimental prototype vaccines may be available for limited testing in humans in 1988, if all steps proceed as planned.

Question 5: Recent research breakthroughs suggest that an AIDS vaccine may be feasible earlier than previously projected. When would you expect to have an AIDS vaccine available? How realistic are those expectations? What is the average time necessary to develop such a vaccine? Is that changing with new technology? When will you know if these expectations will be fulfilled?

Response: If you mean by "have an AIDS vaccine available" that one would be licensed and available for general use, we cannot at this time make a valid estimate for you. As you indicated, new technologies such as recombinant DNA methods and synthetic approaches are leading to findings that may indeed make a vaccine available sooner than would have occurred five or ten years ago. However, once laboratory findings indicate that a particular vaccine may be promising there are extensive animal and human testing requirements that must be met to assure that it is safe, efficacious and worthy of licensure and general use. The length of time required for this process is difficult to estimate because we are dealing with biological systems; and the process is stepwise, requiring a fully successful completion of each step before proceeding to the next. Once animal testing is completed, it generally takes three to five additional years to complete the human testing and have the vaccine licensed. You should recognize, however, that usually only a small percentage of candidate vaccines for any disease successfully complete the entire process. Our hope is that candidate vaccines will become available for animal testing within the next year.

Question 6: Given current vaccine liability problems facing the pharmaceutical industry, what is the likelihood of any manufacturer being willing to produce and assume liability for an AIDS vaccine?

Response: It is still too early for drug companies to assess reliably the extent of potential liability concerns as such concerns will be dependent upon a vaccine's effectiveness, its side effects, and the population to be immunized.

Question 7: Is the Department considering the vaccine liability issue as we move ahead in AIDS vaccine research?

Response: Issues related to vaccine liability are a major consideration of the Department. As a result of a Cabnet Council Working Group effort last year, a legislative proposal addressing the problem of vaccine supply and liability for childhood vaccines was drafted. That proposal (H.R. 4777) is now before the 99th Congress for consideration. The Administration has also drafted a more comprehensive proposal on product liability that would apply to all vaccines were it enacted.

Question 8: What is the status of antiviral therapy?

Response:

The development of drugs which have a proven benefit in curing patients who have viral infections of any kind has proven to be a formidable task. For viruses in general, there are still only a handful of clinically useful drugs (and several of these are still considered experimental). Thus, even before the advent of AIDS, it was recognized that viruses were very difficult targets for therapeutic intervention.

The virus which causes AIDS (HTLV-III) falls into the category called retroviruses. Retroviruses pose special challenges because they become a part of the genetic material of the cells in a patient who gets infected. Thus, once they enter a patient, they can exist, at least in a silent form, for the life-time of the patient. The retrovirus which causes AIDS also has the capacity to establish a chronic infection of the brain, sometimes even before any other clinical sign of the virus is evident. This poses a special challenge for new drug development.

A rational drug-development program for new therapeutic strategies in AIDS became possible in May of 1984 when scientists at the NIH provided formal proof that AIDS was caused by a unique retrovirus (HTLV-III) and developed technologies for producing HTLV-III in large quantities for reproducible drug-testing programs. The search for new drugs that might have a clinical application against the retrovirus which causes AIDS became an exceedingly important priority.

A crash program to develop a rapid assay for assessing anti-retroviral activity of drugs and biologics was undertaken, and such a program was activated by the summer of 1984. Two approaches were taken. The first approach was a short-term strategy of attempting to adapt drugs which had already been used in human beings for another purpose, but which fortuitously had activity against HTLV-III *in vitro.* Such drugs could be considered for use in patients with AIDS immediately without the standard pre-clinical toxicology and development requirements.

The second approach involved a search for potent antiviral agents that had *never* been used in human beings, with special emphasis on deciphering what chemical configuration of a drug might be recognized as a general property that could be exploited in anti-retroviral drug development. The key elements of the drug-screening program are being made available for distribution to any qualified investigator in the United States, and several related screening systems have been established in other research facilities using technologies developed within the NIH intramural program.

To date over 250 substances have been investigated for possible anti-retroviral activity. We have been very pleased to discover that there is, in fact, a family of drugs which are all modifications of the normal building blocks for DNA (drugs that are called nucleoside analogues) and differ from each other in several ways, but nonetheless, all have potent activity against HTLV-III in a test tube, by virtue of a common configuration in one specific portion of the molecule.

One member of this family is called AZT (also called BWA509U and compound S), and it was found to have activity in February 1985. The first patient with AIDS received this agent in July 1985 as part of a pilot (six-week) trial within the NIH Clinical Center. It is worth stressing that this agent had previously never been used in human beings. The results from this pilot trial were published in March of 1986. While it is impossible to draw clinically meaningful conclusions about the safety and efficacy of AZT from the results of a six-week trial, the data suggested that the drug was able to suppress HTLV-III in patients receiving the higher dose regimens of the drug. There was also a suggestion that some patients had a partial restoration of the number and function of the immune system that is ordinarily damaged in AIDS. The study also suggested that AZT had the undesirable potential to suppress the bone marrow function of certain patients, and it is expected that this side effect could be one of the limiting features of this agent. The pilot study proved that AZT could be well-absorbed orally, an important feature given the number of patients who are likely to require long-term therapy once an antiviral agent is proven to be safe and effective. The drug was also shown to have an excellent capacity to get into the fluid that bathes the brain, another potentially important feature given the propensity of HTLV-III to infect the brain.

On the basis of these results, the NIH and the manufacturer (the Burroughs-Wellcome Company) have initiated a multi-center trial to test AZT for six months in patients with AIDS and a precursor form of this disease, called AIDS-related complex (ARC). The study has a double-blind, placebo-controlled design jointly developed by the NIH and the manufacturer, with an NIH sponsored data review committee to periodically review the safety and efficacy results so that an early breaking of the code and conclusion of the study could be accomplished if these steps were warranted.

Two other agents, which have potent activity against HTLV-III in tissue culture, are now being developed for pilot trials in AIDS patients, and it is expected at least one of these (a drug called 2,'3', dideoxycytidine) will be available for pilot trials in the Clinical Center this summer or early fall. The required pre-clinical toxicology steps are now being completed. These trials will be expanded after the completion of the pilot trials. These are part of a set of drugs for which patent applications have been filed on behalf of the Government.

We are continuing our search for new agents, and in particular, are attempting to chemically engineer more potent agents on the basis of the relationship between the structure and function of drugs that has been learned thus far.

Question 9: What priority have you given antiviral research?

Response: Since AIDS is a disease that is caused by a viral infection, possibly sometimes in conjunction with other co-factors, it is naturally assumed that control of the disease will rest on control of the underlying viral infection. This simplistic approach is clearly the best place to start; a logical bias exists that other forms of immunotherapy or immune reconstitution will not succeed unless the viral infection is controlled. Because of this perception, the search for antiviral therapies has been given the highest priority, both in the pre-clinical and clinical arenas.

Question 10: Is that priority high enough given the gravity of the disease?

Response: The gravity of AIDS and its importance to the American public health were recognized very early by the NIH and the current activities are an extension of very long-standing commitment to studying the inter-relationship between immunodeficiency and cancer and the biology of retroviruses. The current priorities reflect the urgency of the problem.

Question 11: In the area of research into effective chemotherapeutic treatments for AIDS, NIH has proposed to begin Phase II trials on a number of available drugs (or on any drug shown to be effective in Phase I trials) in up to 10 Drug Evaluation Units around the country. Is the best priority system and application of resources? After all, effective clinical studies are time and cost consuming. Does this show a well planned clinical study program? We must have drug evaluation units available for the most promising drugs, not clogged with just any drug. Volume does not necessarily mean progress.

Response: The studies that need to be conducted on antiviral agents and other therapeutic interventions for HTLV-III infection will require a systematic and coordinated approach. In many cases, studies will have to be done at several centers, to confirm results and ensure that the conclusions are valid. Other studies will require a multicenter approach simply due to the fact that no one center will have a large enough patient population to conduct the study in one place.

Past experience with trials of antiviral agents and vaccines has convinced the NIAID that the establishment of these AIDS Treatment Evaluation Units represents the most suitable paradigm for the tasks at hand. These units will be guided in their efforts by the deliberations and priority setting of the AIDS Drug Selection Committee. It is likely that, as these units mature, each will likely demonstrate a particular expertise or unique set of clinical interests. We see this as enriching the clinical efforts and offering the broadest possible base of investigation upon which to develop an agent. These units will not be "clogged with just any drug" but evaluating agents that are most in need of testing in the most expeditious manner possible.

Question 12: Research into psychological aspects of AIDS has traditionally gotten a small percentage of overall AIDS appropriations. Yet its importance grows as public concerns about AIDS and the incidence of disease increases. What plans are there for this type of research?

Response: There is considerable funding in FY 1985 already committed to psychosocial research on AIDS by both the National Institute of Mental Health (NIMH) and the National Institute on Drug Abuse (NIDA). While most of the more than 90 submitted grant applications for FY 1986 are pending review, psychosocial aspects of AIDS represents a significant proportion of these applications. Because these applications are from previously funded NIMH and NIDA researchers, it is expected that a high proportion of these applications will be approved. Funding decisions are expected this summer. Examples of the psychosocial research grants currently funded include: 1) Longitudinal Psychosocial Study of AIDS Patients (University of California, San Francisco); 2) Coping Strategies in AIDS Patients (University of Michigan); 3) AIDS Risk Groups, Predicting Changes in Sexual Behavior (Memorial Sloan Kettering); 4) Impact of AIDS on Sexual Behavior of Gay Men (University of California, San Francisco); 5) Mental Health Effects of AIDS in At Risk Homosexual Men (Columbia); Prospective Psychosocial Study in Men at Risk for AIDS (University of California, San Francisco); or, 7) Psychosocial Stress and Immune Responsiveness (Stanford). Because of the recent evidence documenting a direct infection of the brain by the causative agent for AIDS, the ongoing focus of research by these institutes will intertwine the psychosocial and biologic focus important to advancing our fight against AIDS.

Question 13: If it is not planned, why not?

Response: Please see answer to question 12.

QUESTIONS BY SENATOR HATCH

FDA QUESTIONS

Question #1:

How many product license applications or product license amendments have been received by the Office of Biologics in the last 12 months?

Question #2:

Of these applications and/or amendments how many have been approved or rejected as of April 1?

Question #3:

What have been the reasons for the rejections?

Response:

In the last year (April 1, 1985 to April 1, 1986): For vaccines, none have been received. For therapeutic drugs, one has been submitted. This application was not approved since the data did not support the claim of product effectiveness. For the diagnostic category, seven applications and/or amendments for new or significantly revised AIDS test kits have been submitted. Of these, two have been approved; and five are currently under review.

Question #4:

Are there any product license applications or product license amendments that have been in the review process for more than 90 days?

Question #5:

If so, how many and why?

Response:

Yes. In the category of diagnostic tests, three applications have been in the review process more than 90 days. These three applications are for test kits using new production technologies and/or test methodologies which have necessitated the submission of additional information. There are currently no applications pending in the vaccine or therapeutic drug category.

Question #6:

Are there any applications and/or amendments that have been under review at the Office of Biologics for more than six months?

Question #7:

If so, how many and why?

Response:

Yes. One of the applications listed in question 5 has been in the review process for more than six months. The review of this application has been held in abeyance with agreement from the manufacturer while production problems are being resolved.

Question #8:

Given the urgency or solving the problem of a uniformly fatal disease like AIDS, has the FDA considered establishing a review period which reflects the need to distribute accurate biological tests in a special or short period of time?

Response:

FDA has been extremely sensitive to the gravity of the AIDS problem and we have expedited all requests for the study of any product for this condition. On a number of requests for the study of experimental drugs, we have given approval in only five days. And, the first ELISA tests for detecting AIDS antibodies were approved just weeks after receiving the final clinical trial data. All AIDS applications would receive special handling and any product that could be shown safe and effective for treating AIDS would be approved as expeditiously as possible.

Question #9:

Has the FDA considered forming a special task force to review AIDS related product license applications and amendments to expedite the review and approal of these urgently needed tests?

Response:

FDA has already formed several task forces both to help expedite reviews and to share scientific knowledge of the disease.

Question #10:

If so, what action has been taken to implement a more efficient review system?

Response:

A number of steps have been taken in the last few years to implement a more efficient review system at FDA. We don't think any further changes are needed to deal specifically with the AIDS issue. Essentially, we believe that an effective product for AIDS will receive expeditious handling with our existing system.

Question #11:

If not, why not?

Response:

See response to question 10.

Question #12:

Have any alternatives other than a special task force been considered?

Question #13:

What has the FDA done to capitalize on or enhance the results of NIH research?

Response:

The thing the FDA has done is to work very closely with NIH and the academic community. FDA scientists are working day-by-day with Dr. Fauci, and other NIH scientists working on AIDS. FDA scientists are attending the mettings that NIH schedules on AIDS. NIH scientists are attending FDA-sponsored AIDS meetings and there is no gap in information. In addition, NIH, FDA and CDC scientists are actually helping in testing drugs and developing clinical data needed for ultimate approval of drugs. With drug Pentamidine, for example, which was a very important drug to treat AIDS-related opportunistic infections, FDA and CDC generated the primary data needed to support the final approval.

Question #14:

How many of the product license applications or amendments involve a technology not currently used for the diagnosis or screening of AIDS?

Response:

Two pending applications for AIDS test kits use a test methodology not currently approved for the diagnosis or screening of AIDS antibody.

Question #15:

Is the FDA equipped to review the new line of non-enzyme diagnostic or screening tests? Equipped in the sense of current technology, education and experience or reviewers.

Response:

Yes.

Question #16:

If not, what is necessary to provide for the review of this techonolgy?

Response:

Not applicable.

Question #17:

In view of the need for tests that diagnose an AIDS carrier or victim with great accuracy, what has the FDA done to solicit and process tests which claim to screen non-high risk groups for the AIDS virus?

Response:

The FDA has encouraged all kit manufacturers to develop test methodologies that would provide greater assurance that a positive test result means the AIDS antibody is present. The FDA scientific staffs have been available to meet with manufacturers and to provide technical assistance when applicable. The two test kits discussed in question 14 were designed specifically to provide greater assurance of a true positive result. These two kits are undergoing an expedited review.

Question #18:

Has the FDA received any applications for confirmatory diagnostic tests?

Response:

The FDA has received two applications (see question 14) for tests using new methodologies which may be improvements over existing screening tests in identifying antibody specific to the AIDS virus. Review of the data submitted to date does not clearly demonstrate that these tests are in fact "confirmatory" diagnostic tests.

Question #19:

How soon might a confirmatory test be approved for marketing?

Response:

Any license application submitted for a diagnostic test which is labeled by the manufacturer as a confirmatory test is given priority in the review process. The length of the approval process is dependent on the adequacy of the data submitted. Since the purpose of confirmatory testing is to verify the validity of a previous positive test result, data with a greater confidence level are necessary. The FDA reviews of the two tests discussed in question 14 are expected to be completed in the next few weeks.

Question #20:

As you are well aware, before today and again reminded by our first panel of witnesses, contamination of the blood supply and blood products with the AIDS virus has been a constant source of concern. An important element in maintaining a good blood supply is blood testing. Yet it has come to the Committee's attention that the review of kit batches has grown from five working days to almost ten working days. What has caused the sudden increase?

Response:

The increase in the lot release time was due primarily to the increased number of manufacturers being licensed to produce test kits. This meant that the same number of test kits were being released by FDA, but that any single manufacturer might have experienced a longer release time.

Question #21:

Again, given the urgency for the diagnosis and treatment of AIDS patients, isn't ten days unduly lengthy?

Response:

Considering the significance and impact of the test results on the blood supply, the extent of the review and testing required to assure accurate test results, and the number of test kits being submitted for review, ten days is not an undue length of time for batch release.

Question #22:

Do you forsee returning to a five day turn around for batch approval?

Question #23:

If so, when?

Response:

Additional personnel have been assigned to perform FDA testing and review for the release of AIDS test kit batches. This has resulted in an increased number of test kit batches being released with a shorter review and approval timeframe.

QUESTIONS BY SENATOR HATCH

HEALTH CARE AND CARE DELIVERY SYSTEM QUESTIONS

Question 1:

Medicaid is currently reimbursing States at a rate of about $100 million annually in AIDS-related costs, most of them incurred in expensive in-patient hospital settings. That cost will inevitably grow, but it could be reduced drastically if States were permitted to use Medicaid to pay for costs incurred in far less expensive home-care, hospice and other such settings. This out-patient model would be studied in four 1985 demonstration projects that the Administration now proposes to rescind. What is the wisdom of cutting relatively inexpensive programs whose results could save the Government hundreds of millions of dollars over the next several years?

Response:

The recision request referred to was not agreed to by the Congress by April 15, 1986. Therefore, the request is now moot.

Question 2:

Doesn't the Government, in fact, have a responsibility to encourage the reduction of costs, and a role in facilitating tax reduction?

Response:

Yes, and the recission was proposed as part of the President's overall budget reform plan to curtail Federal spending.

Question 3:

What is being done about this?

Response:

We plan to make available $15.3 million to support AIDS Service Demonstration Program projects in the four Standard Metropolitan Statistical Areas reporting the highest number of AIDS cases.

A notice of Availability of Funds will be published in the Federal Register. Then, the final program guidelines and grant application instructions will be prepared and distributed. The actual notice of grant awards is expected to be issued in September of this year.

QUESTIONS BY SENATOR HATCH

PUBLIC EDUCATION AND PREVENTION ACTIVITIES QUESTIONS

1) Question:

What private sector initiatives have been undertaken in the areas of AIDS public education and prevention, and how, if at all, are they coordinated with government efforts?

Answer:

Private sector initiatives on AIDS have increased recently because of the growing impact of the disease on issues such as insurance, employment, and school attendance, to name a few.

Large corporations have provided financial support to develop educational programs for various audiences. For example, Levi Strauss and other corporations funded a program, AIDS in the Workplace, developed by the San Francisco AIDS Foundation. Although we do not have good information on private sector initiatives across the country, it must be assumed that similar projects are being supported in many communities, especially those with a high incidence of AIDS cases.

The Public Health Service and the American Red Cross are jointly sponsoring a mass media campaign to educate the public about AIDS, particularly to allay unwarranted fears and to control the further spread of the disease. Three television public service announcements were released in March of this year, and complementary posters were produced for distribution in public health facilities and other outlets. Three additional radio and television public service announcements are being developed, as well as spots and print ads for local newspapers. The new public service announcements are aimed primarily at young people to alert them to the dangers of casual sex and drug abuse. A fourth spot will deal with the safety of donating blood. A recent survey by the American Association of Blood Banks revealed that 34% of the population erroneously believe that AIDS can be contracted by donating blood. We plan also to produce additional posters and other print materials to reinforce our messages. All of the Red Cross/Public Health Service materials promote PHS's toll-free hotline, encouraging people to call this number for accurate information about AIDS and how to prevent its spread.

2) Question:

Who is doing this? We want copies of plans.

Answer:

Fiscal Year 1986 PHS plan and Red Cross plan attached.

Revised
November 1985

AIDS PUBLIC INFORMATION PLAN
OFFICE OF PUBLIC AFFAIRS
PUBLIC HEALTH SERVICE

Fiscal Year 1986

OBJECTIVES: To inform the American public regarding Acquired Immune Deficiency Syndrome (AIDS) sufficiently to create a widespread awareness and understanding of the nature of the syndrome, its suspected means of transmission, the relative threat it poses to various populations and to the public health. The aim of this public information program ultimately is to help prevent and control AIDS, by informing the public about specific behaviors to reduce the threat of AIDS to individuals.

An epidemic similiar to that of AIDS has never before been experienced. Because of the nature of two groups at highest risk (gay men and IV drug abusers), because of the high fatality rate (over 70% after 2 years in those who meet the CDC definition of AIDS), and the high costs of treating AIDS patients, AIDS has caused not only a threat to the public health, but an exceedingly high toll on the public, including emotional, social and political implications. AIDS has brought with it problems that relate to confidentiality, sexual mores, medical practice (with reference to blood transfusions, patient counseling, organ donations and others), and civil rights issues. As the number of cases and the number of deaths increase, and as AIDS spreads geographically, these problems will increase.

Only by paying strict attention to public attitudes (including those in the communities at risk, the health community, and others affected directed by AIDS), can the PHS and other responsible groups influence public perception, and therefore, personal behavior necessary to control the AIDS epidemic.

Target Audiences: The nature and effects of AIDS and the public response experienced to date regarding attitudes toward the syndrome and to at risk populations indicate the desirability of targeting selected information and appropriate message to several audiences. Following are brief descriptions of those audiences and messages: (Detailed public information projects are attached to plan).

I. General Public, male and female, aged 14 and older not specifically identified as being at risk--This group includes certain subgroups that will require additional information and targeted messages, but in general the public requires basic awareness of AIDS as being an infectious, sexually transmitted, blood-borne affliction. The fact that gay and heterosexual populations may be at risk for AIDS because of sexual exposure is a message of special importance to all segments of the public. So, too, is the danger posed by IV drug abuse. The safety of blood donation and the HTLV-III antibody and subsequent tests have created a need for information directed at the public, both those who donate blood and those who may need transfusions or blood products in the future.

The major message for the public should include careful descriptions of behavior that may put individuals at risk--i.e., multiple sexual partners and exchange of body fluids. This message is especially important to young people who are just becoming sexually active, and who have not experimented with IV drugs.

Another purpose of providing information is to prevent confusion about risks particularly where such confusion needlessly reduces blood donations, interferes with patient acceptance of medically necessary blood transfusions, and stigmatizes at risk groups so as to interfere with their functions and relationships in society. Subgroups of this target audience, not treated separately elsewhere, include:

-- Blood donors not at risk;

-- Persons who frequently encounter at risk populations as a result of their type of work, place of work or residence, or recreational pursuits;

-- Persons who encounter populations at risk as a result of family relationship or friendship (not including sexual partners).

II. Homosexual and Bisexual Male Portion of the General Public--This group requires AIDS information sufficient to understand the nature of the syndrome, whether their sexual activity renders them at high risk, the precautions recommended for avoiding contracting or passing along the syndrome, symptoms of the syndrome, significant research findings, and awareness that significant effort is being applied to discovering the cause and cure of the syndrome.

III. Abusers of Intravenous Drugs--This group needs to be informed of the dangers of AIDS, to themselves and their sexual partners; and encouraged to stop using drugs (or enter treatment programs~~).~~

IV. Hemophilia Patients, Blood Recipients, and Those with Positive AIDS Antibody Tests--These groups need to know the risks involved regarding the potential for contracting AIDS, and have access to understandable explanations of the syndrome, particularly precautions that blood laboratories take to protect the purity of their products.

Information for seropositive donors will continue to be necessary, as will efforts to step up blood donations should a situation arise where people become frightened about becoming exposed to AIDS through donating blood.

V. Sexual Partners of Risk Group Members and Heterosexuals with Multiple Partners--These groups (primarily heterosexual partners of bisexual men, drug abusers, and hemophiliacs; and heterosexuals with multiple sex partners) need information on risk to them and to possible offspring. In addition to steady sex partners, information must also be directed to people who may be exposed through casual sexual contact, and to people whose sex partners may have multiple partners. Prostitutes and their clients are part of this group, as well as part of the IV drug group.

VI. People With Symptoms of AIDS and AIDS Patients--These groups need information on their disease process, help in dealing with the emotional impact of AIDS, and related subjects. Particularly important is the need to advise those infected with the AIDS virus on the possibility of transmitting the virus to others.

VII. Health Workers--This audience encompasses a wide range of occupations and professions that require information for diagnosing, treating and counseling AIDS patients and regarding self-protection against the syndrome. There is a particular need to keep this group up-to-date on research implications re testing, antivirals and other therapeutics, and to counter misconceptions about AIDS among this group which interfere with providing normal care to AIDS patients.

VIII. Others Whose Jobs Bring Them In Close Contact With At Risk Populations, Family and Friends of Risk Group Members--This group, which includes such occupations as police, prison and other security guards, certain laundry and custodial workers, and similar service personnel, usually has less health information and understanding than most of the medical audiences. The group needs basic information about the nature of AIDS and its means of transmission so that they will not harbor unnecessary fears about their work and the at risk individuals with whom they deal.

# # #

FY 1986 - Information Projects/Activities/Materials Concerning AIDS.

The production and distribution of various public information materials is important to the implementation of a national plan to prevent and control AIDS. Plans for these materials are outlined below. Of equal importance are the daily public affairs functions carried on at the PHS level and at the five agency levels. These functions include working with the press in preparing accurate stories on AIDS, preparing releases on AIDS research findings and other materials for the press, performing liaison functions with various groups carrying out public information and education programs on AIDS, preparing correspondence with Congress, organizations, and the public and similar activities. Coordination of the various activities of the PHS agency public information activities is essential, as is staying up-to-date on PHS activities in AIDS across agency lines. These activities form a framework within which a cohesive public information plan can be executed.

Following is a proposed list of projects for FY '86. These projects may be modified as new scientific information becomes available.

A. All segments of the public (age 14 and above) including sexually active heterosexuals (male and female) with multiple sex partners; persons not at risk who may encounter risk group members and AIDS patients through work/residence/recreation, family and friendship; and blood donors not at risk.

Need: Provide information about transmission of AIDS, and current research findings on all aspects of AIDS, to:

- Prevent and control spread of AIDS
- Reduce needless fear
- Avoid stigmatizing people at risk and those with AIDS

Information/Education Plan

- Form ad hoc communications group to advise PHS public affairs officers and key management staff on needs and methods for reaching various segments of the public

Cost: $5,000 (PHS/OPA)

General Public

1. "Facts About AIDS," (2-4 page Fact Sheet) Update regularly and distribute widely through PHS agencies, to opinion leaders, interested groups and all segments of the public. (Also publish in Spanish)

   Cost: $15,000 (CDC, with all PHS agencies)

- o Distribute "Facts" nationwide through Supermarket Communications, racks in supermarkets around the country (5800 stores), for 1 full year.

  Cost: $260,000 (PHS/OPA)
  (or less depending on funds)

2. Publish series of flyers on various aspects of AIDS and distribute widely.

   (a) AIDS and IV drugs, What's the Connection*
   (b) AIDS and the Blood Supply
   (c) AIDS and Gay and Bisexual Men
   (d) AIDS and Heterosexuals
   (e) Health Care Workers and AIDS
   (f) AIDS and Your Job
   (g) Caring for the AIDS Patient at Home
   (h) AIDS and Children
   (i) If Your HTLV-III Antibody Test is Positive

- o Pretest flyers before distribution

  Cost: $50,000 (PHS/OPA, with *ADAMHA)

3. Plan and Implement Master Distribution Plan for all AIDS material. Encourage PHS agencies to distribute AIDS materials.

   Cost: NA (PHS/OPA)

- o Distribution of AIDS material, in addition to Agency work, will require contract help at a minimum, and perhaps institution of an AIDS clearinghouse. (see attached description of proposed clearinghouse)

  Cost: $50,000 minimum (PHS/OPA)

4. AIDS Hotline: Continue to sponsor with up-to-date information. Promote use of Hotline nationwide.

   Cost: $200,000 (CDC, with PHS/OPA)

- Conduct workshops for Directors of AIDS Hotlines nationwide

  Cost: $20,000 (CDC)

5. Four Channing-Bete publications on AIDS: Work with publisher to update regularly. (Purchase and distribute limited number of booklets, which are sold nationwide). Also purchase booklet on drugs and AIDS, commissioned by State of New Jersey.

   Cost: $55,000 (CDC)

6. Produce slide talk for the public on AIDS. Distribute through National Audiovisual Center.

   Cost: $10,000 (PHS/OPA)

7. Improve national press capability for reporting AIDS stories in print and electronic media.

   a. Step up issuance of PHS press releases.

   b. Scientific press seminars to update science writers (print and broadcast media) to assure accurate and adequate coverage of AIDS research findings. (6-12 during year.)

   c. For seminars, produce media kits, and also mail widely (press, opinion leaders, Congress, the public)

   d. Renew publication of "AIDS Information Bulletin" for distribution listed above

   e. Place Secretary, Assistant Secretary for Health, all major PHS spokesmen on major network and local TV/radio shows, and set up interviews with influential reporters and columnists.

   f. Prepare OpEd pieces, letters to the editor, and communications with editorial page writers to counter misinformation on AIDS and PHS role.

   g. Compile subject-related MMWR articles.

   Cost: $20,000 (All PHS/OPA)

8. Conduct mass media campaign in conjunction with American Red Cross

   - TV and Radio PSAs

   - Posters and Car cards (5-6 messages in three waves)

- Pretest for appropriateness of messages, acceptability of format, etc.

Cost: $100,000, each, PHS and Red Cross (OPA/PHS)

9. Analyze existing public opinion polls to identify knowledge gaps

Cost: NA (CDC)

10. Support Gallop Poll to compare knowledge with June 1985.

Cost: $20,000 (CDC)

11. Conduct risk reduction/media workshop for State and local health officials who deal with media.

Cost: $40,000 (CDC)

12. Conduct conference for national health organizations such as Red Cross, AMA, American Cancer Society et al to present AIDS information and solicit cooperation in informing/educating their members.

Cost: $5,000 (CDC/PHS/OPA)

13. Prepare speech blocks on AIDS for Agency and Regional PHS officials and HHS officials to intensify and coordinate messages on AIDS.

Cost: N/A (OPS/PHS)

B. Homosexual and bisexual men, the group that has had 70% of the AIDS cases.

Need: Access to the latest AIDS information to help individuals modify behavior that puts them at high risk. Also includes the "worried well," and those with AIDS or with early symptoms.

- Include gay communications experts (also Hispanic and Black) to work with PHS public affairs officers on reaching these audiences.

1. Facts About AIDS - see earlier description
2. Hotline - see earlier description
3. Develop booklet on AIDS for gay and bisexual men--see earlier description.
4. Special outreach efforts to reach black and Hispanic gays, and adolescent youth who may become sexually active (these

groups may not be reachable through usual gay channels).

- o Produce flyer above, and "Facts" in Spanish.

  Cost: $20,000 (OPA/PHS and CDC)

- o Work with COSSMHO and other Hispanic health groups to reach Hispanics;

- o Develop liaison with groups that may reach black gays and bisexual men--Contract with Black gay organizations to produce prototype educational information.

Cost: $20,000 (OPA/PHS)

5. Respond to mental health needs of gay AIDS patients (produce material for mental health and medical community)

- o See later description on "Coping With AIDS."

- o Also "Caring for the AIDS Patient at Home"

Cost: (ADAMHA/PHS)

- o Distribute on request resource directory on AIDS services, funded last year.

CDC has separate plan for community-level health education, risk reduction needs and plans.

C. IV Drug Abusers (Almost nothing has been done to reach this group. ADAMHA is planning strategy)

o Convene group of advisors to work out specific plans for reaching this hard to reach risk group.

1. Develop various public information materials for this group, including posters, flyers and other materials to use in drug treatment centers and other places where drug abusers may congregate. Also reach recreational drug users. (See earlier flyer on drugs)

Cost: (ADAMHA, with PHS)

D. Hemophiliacs, those who need blood transfusions and donors with seropositive test results.

1. Continue Hemophilia Information Exchange to gather and exchange information on AIDS for physicians to improve patient care and enhance coordination of research; expand audience to others with a responsibility to provide care for hemophiliacs and families.

2. Work with organizations representing blood recipients and blood collection groups to provide public with information on the safety of the blood supply.

3. Develop leaflet on AIDS and the Blood Supply--see earlier description.

5. Work with blood collection agencies to encourage blood donations, to assure that supply does not drop because of AIDS fear.

(PHS-all agencies)

E. Sexual Partners of High Risk Group Members and Heterosexuals With Multiple Sex Partners

Many in this group are women, not targeted by earlier information efforts because of the much higher incidence of AIDS in men.

- Wives or regular sex partners of IV drug users, hemophilia patients, bisexual men and heterosexuals at risk because of multiple sexual partners must know the risks for getting AIDS, methods of transmission, dangers of pregnancy and transmission to children.

1. Provide AIDS information through channels mentioned in general public section (See flyer--AIDS and Heterosexuals, earlier)

2. Provide information through STD clinics, family planning agencies, etc.

Cost: (PHS-Population Affairs)

3. Convene special briefing for women's press on AIDS transmission (add columnists and feature writers)

Cost: $5,000 (OPA/PHS)

4. Plan effort to reach college and university youth, and other young people with AIDS information.

Cost: NA (OPA/PHS)

F. AIDS Patients or those with ARC: (See ADAMHA strategy)

1. Produce mental health materials for health care providers to increase sensitivity of these groups toward patients (see "Coping With AIDS" earlier.)

2. Make resource directory available on request (mentioned earlier)

3. Increase efforts to minimize fears directed to this group by the public (see general public section)

G. Health Care Providers: This group needs the latest information on--

- o Proper counselling of high-risk persons and AIDS patients
- o Avoiding risks in handling body fluids and tissues
- o Risk avoidance for eye-care personnel, dentists, surgeons and auxiliary health care workers.
- o HTLV-III antibody testing
- o Diagnosis and treatment of patients
- o Research findings on vaccine and treatment modality development.

1. Update videotape "What If the Patient Has AIDS," and renew distribution through National Audiovisual Center

Cost: $15,000 (OPA/PHS)

2. Publish latest information on AIDS in science journals, MMWR, FDA Drug Bulletin, etc

Cost: NA (all PHS)

3. Distribute AIDS material through PHS channels to all scientific organizations, State and local officials, other health agencies, hospitals, etc. (Dear Doctor letter, FDA; JAMA column; voluntary meeting--see earlier; etc.)

(all PHS)

4. Develop AIDS Information Service for MINET and other electronic information services (see attachement)

Cost: $20,000 (CDC)

5. Renew NIAID outreach programs for health care providers, other occupational groups, and the public

(Boston, Washington -- Spring 1986)

(New York, San Francisco -- Summer 1986)

- o Produce videotape of same and offer free distribution

Cost: $500,000 (NIAID/NIH)

6. Produce material on mental health needs of AIDS patients "Coping With AIDS"

   Cost: $20,000 (NIMH)

7. Explore Hospital Satellite Network and other teleconference facilities for AIDS information use.

   Cost: (OPA/PHS)

H. Other Occupational Groups--for groups who feel at risk for AIDS because of on-the job contact with risk groups or AIDS patients, special efforts must be made to counter misinformation and convey information on necessary risk-avoidance.

1. Revise videotape "AIDS and Your Job" and distribute through NAC

   Cost: $10,000 (OPA/PHS and CDC)

2. See flyer earlier, "AIDS and Your Job"

3. See outreach, NIAID, above

4. Provide all AIDS information to prison officials, police groups, paramedical groups, etc.

   Cost: NA (all PHS)

NATIONAL AIDS INFORMATION CLEARINGHOUSE PROPOSAL

PURPOSE

Develop and implement a National AIDS Information Clearinghouse. The Clearinghouse would have three major functions:

1. Serve as a general information service, providing the latest information on subjects such as AIDS surveillance, risk factors, legislative activity, prevention guidelines, etc.

2. Gather information on programs and materials that health agencies or organizations have used to effectivly address issues such as:

   Delivering prevention messages to high risk groups, medical care providers, blood donors, the general public.

   Working with representatives of schools, hospitals, prisons, and similar institutions to assure that appropriate public health decisions are made and that AIDS patients are not discriminated against.

   Working with community organizations, professional groups or the media to deliver prevention messages or to assuage inappropriate community or individual concern.

   Using the results of HTLV/III antibody testing for control, educational and counselling programs.

   Using task forces or other working groups to get community input into decision making.

3. Disseminate the information that is developed (in 2 above) to health agencies and other organizations by methods such as newsletters, special mailings, workshops, meetings, telecommunications systems or other appropriate mechanisms.

CDC AIDS INFORMATION SERVICE

To expedite the development of a CDC AIDS Information Service, we propose a reasonably simple beginning, and then an expansion of the system as we gain experience with it. Options that would be available are:

1. CDC AIDS Weekly Surveillance tables. These are currently available on the CDC Information Service and would be transferred to this Service.

2. National Referral Directory of AIDS-Related Services, prepared by the National Gay Task Force for the U.S. Conference of Mayors. Includes listing by State Organizations. Can be accessed by State designation, National Organizations, and Federal Agencies.

3. List of conferences, meetings, and other AIDS-related events.

4. Facts on Aids.

5. CDC Risk Reduction and Prevention Guidelines, broken down by subject and target audiences.

6. Reverse chronological MMWR reports on AIDS. Should also be accessible by subject.

7. CDC Surveillance Definition of AIDS.

As we gain experience with this service, there are other informational items we should consider adding, such as State or local health department reports, research reports, funding availability, etc. We might also make it interactive so that it could be used for reports to us.

AMERICAN RED CROSS
AIDS PUBLIC EDUCATION PROGRAM

I. OVERVIEW

The acquired immune deficiency syndrome (AIDS) epidemic has rapidly become one of the most complex public health problems in our nation's history. As of December 1985, more than 15,000 cases of AIDS had been diagnosed, and more than 7,500 people had died of the disease. If the present rate continues, by the end of this decade more Americans will have died from AIDS than were lost in the Vietnam conflict.

As the number of fatalities rises, public fear escalates. While surveys indicate an increase in public knowledge about the disease, ignorance and myth still prevail. For example, while people report that they understand how AIDS is spread, many of them continue to harbor unwarranted fears about donating blood. How do we allay these fears, provide the public with the information they need to reduce their risk, and assist those affected by the epidemic?

The American Red Cross saw a critical need for a comprehensive education program to inform the public about AIDS, particularly since no vaccine to cure AIDS has been developed. AIDS education programs had so far focused on high-risk groups, primarily homosexual and bisexual males in large urban areas. No organization had yet focused its efforts on the needs of the general public for reliable information about the risk of AIDS. The Red Cross responded to this need by declaring AIDS public education a new corporate objective. In taking this decisive action, the Red Cross has made a long-term commitment to meet this challenge by mobilizing its national network of 3,000 chapters to conduct an educational outreach program.

This national network of chapters is capable of providing emergency relief and educational services to all parts of the country. This service delivery system has a long track record of responding to community needs for standardized education in health and safety areas such as swimming, lifesaving, first aid, CPR, and, more recently, in health promotion and disease prevention areas such as nutrition, high blood pressure, maternal and child health, and accident prevention. The actual delivery of these educational programs is provided almost entirely by trained volunteers drawn from both the lay public and from various health professions and organizations with interest and expertise in these subjects.

The challenge is to create an effective and far-reaching national network for AIDS public education that can deliver information concerning the real dangers and risk factors to the general public and guide individuals on how to best protect themselves and their families from contracting the disease. Such a network must, we believe, involve various segments of the community, including schools, businesses, corporations, health care providers, public policy makers, and public assistance personnel. This proposal addresses the challenge of implementing such a national AIDS Public Education network.

II. THE PROBLEM

A. What is Acquired Immune Deficiency Syndrome?

AIDS is not a single disease but a complex of diseases generally leading to death. It was first recognized in 1981 as an unexplained progressive immunodeficiency disorder associated with Pneumocystis carinii pneumonia and/or Kaposi's sarcoma, a rare form of cancer. It has been established that the basic cause of AIDS is a newly discovered virus called human T-cell lymphotropic virus, or HTLV-III. French researchers, the first to isolate the virus, refer to it as the lymphadenopathy associated virus (LAV), but these isolates and HTLV-III are clearly from the same virus family. The AIDS virus infects and destroys certain white blood cells that are essential for the functioning of the body's immune system. When the immune system is severely depressed or destroyed by HTLV-III, the body becomes vulnerable to serious opportunistic infections, rare forms of pneumonia, and cancer.

Since its emergence as a public health problem, there has been concern that the AIDS virus will spread from the originally defined high risk groups (homosexual and bisexual males, intravenous drug users, hemophiliacs, and recipients of blood and blood products) to the general population. This does not appear to be the case; the great majority of patients with AIDS has remained relatively constant within the high risk groups. Since the introduction of the HTLV-III antibody test to protect the blood supply, recipients of blood are no longer considered a high risk group.

As more is learned about the virus, it has become apparent that there is a broad spectrum of clinical responses to it. Most individuals infected with the virus are asymptomatic and show few, if any, immunologic abnormalities. A second group of individuals exhibits relatively mild symptoms of the illness, while a third group develops the severe AIDS syndrome.

The magnitude of the AIDS crisis is heightened by the latest Centers for Disease Control (CDC) estimates that as many as 1 million persons have been exposed to HTLV-III and may be carriers of the virus. The majority of these infected individuals are either homosexual or bisexual males, intravenous drug abusers, or sexual partners of individuals in the high risk groups, most of whom are unaware that they have been exposed and carry the virus. These are the "silent carriers." It is estimated that perhaps between 10 to 20 percent of this group will develop the severe form of AIDS, which is believed to have an incubation period of up to five years.

The mortality rate is staggering: Seventy-three percent of patients diagnosed with AIDS before January 1983 have died; not one, as far as we know, has recovered. Once infected with the virus, a person is believed to be infected for life.

B. Who Gets AIDS?

Since 1981, the Centers for Disease Control has been collecting information on AIDS. Ninety-four percent of persons with AIDS belong to one of the following groups:

- Sexually active homosexual and bisexual men with multiple sex partners (73 percent)
- Present or past abusers of intravenous drugs (17 percent)
- Patients who have had transfusions with blood or

blood products (2 percent)

- Steady sexual contacts with persons with AIDS or persons at risk for AIDS (1 percent).

Approximately 6 percent of persons with AIDS are not known to belong to any of these groups, but researchers believe that in these cases transmission of the disease occurred in ways similar to those in high-risk groups. Some patients died before comprehensive medical histories could be completed and probably belonged to one of the high-risk behavior groups. Pediatric cases of AIDS appear to occur in infants and children whose mothers belong to one of the high-risk groups, or who, themselves, have received blood transfusions.

Given the controversy surrounding AIDS, it is critical that the general public be informed about the disease and its transmission so it can respond to the crisis in a reasoned and responsible way. Dr. James Mason, Director of the CDC and former Acting Assistant Secretary for Health of the U.S. Public Health Service, has noted, "AIDS is not easy to catch. People who are frightened of friends, co-workers, and family members who may be at risk of AIDS are suffering unwarranted fear. This is the fear we need to do away with." This is one of the underlying goals of the Red Cross AIDS Public Education Program: to reduce irrational fears about AIDS among the general public. The ultimate goal is to educate the general public and reduce the spread of the AIDS epidemic.

The initial Red Cross experience with AIDS resulted from recognition of the problem of AIDS transmission by blood and blood products. In coming to grips with that problem, the Red Cross played a leading role in developing and implementing policies to prevent voluntary blood donation by persons at risk of AIDS. Later, when the AIDS virus was identified, Red Cross was in the forefront of development and evaluation of a test for infection with the AIDS virus. This test was approved by the Food and Drug Administration in March 1985, and was immediately implemented throughout the Red Cross Blood Services system. We have gained excellent experience with testing almost 4 million donations (6 million projected per year) from members of the general public. This area of Red Cross service will continue to keep us at the forefront of scientific knowledge and practical experience in testing for infection with the AIDS virus and in a variety of related issues (test sensitivity and specificity, epidemiology, confidentiality, donor and patient rights, and transfusion safety).

III. THE GOALS AND OBJECTIVES

The AIDS Public Education program builds on the unique strength of the national Red Cross network, which consists of 3,000 chapters, to address the various needs of the general public to deal effectively with the AIDS crisis.

Specifically, the goals of this program are:

- to provide reliable information about the risk of contracting AIDS;
- to demystify the disease and reduce unwarranted fears surrounding AIDS; and
- to slow the spread of the HTLV-III virus that causes AIDS, and the spread of the disease itself.

These goals will be accomplished through a cooperative effort linking the Red Cross chapters with organizations within the community, including schools, corporations, business groups, and trade associations, that are grappling with the many issues surrounding the AIDS epidemic.

To attain these goals, eight primary objectives will be met by the Red Cross AIDS and Public Education Program:

1. Utilize cooperative relationships among the Red Cross chapters, national and local organizations, and communication channels within the community to disseminate information on AIDS; facilitate forums to examine the implications of the AIDS epidemic for the community at large.
2. Develop and disseminate a series of Educational Outreach Packages for distribution to the community. These will consist of a minimum of four slide/tape shows reprints of informative materials, and targeted materials for special populations, including schools and adolescents, employers and employees, health care providers and social workers, and public policy makers. These packages will be distributed to the Key Resource Chapters and made available to the other Red Cross chapters on request.
3. Produce a one-hour video documentary on AIDS that will be aired on local PBS stations and made available for cable television and other networks. This documentary will also be used for non-broadcast educational purposes by the chapters at community forums, seminars, and training sessions for Red Cross staff and a variety

of groups within the community. Complementary materials for schools, business groups, and health service providers will be developed and distributed with the videotape.

4. Deliver on a quarterly basis a series of Media Packages to the public relations directors of all chapters for their distribution to the print and broadcast media.
5. Establish a National Resource Data Bank on AIDS that will list chapter-produced and other materials, individuals at the local level who can serve as a resource for conferences and other groups within the community who are involved in AIDS education, and include a bibliography on AIDS literature.
6. Develop and deliver training programs for Red Cross staff and volunteers to prepare them for planning and conducting the AIDS Public Education Program. Within the first year of this effort, the program will have available: (a) one professional staff person or volunteer at each of the Key Resource Chapters and largest field units (450 total) who will be responsible for AIDS education and outreach; and (b) 25 experts who can provide guidance and information to the chapters for community outreach.
7. Deliver on a monthly basis a series of reliable and concise Information Packages for distribution to the chapters. These information packages will include such up-to-date information on AIDS as Centers for Disease Control guidelines, position papers, and policy

statements that will enable Red Cross staff to answer individual and community questions and concerns about AIDS.

8. Refine measurement tools to monitor the distribution process and evaluate the knowledge, attitudes, and behavior changes of program participants.

IV. THE PROGRAM PLAN

The goal of the comprehensive AIDS Public Education Program is to educate the general public about AIDS. The primary vehicles to achieve this goal are:

- Community Outreach
- Mass Media Activities (Television, Radio, PSAs)
- Training for Red Cross Staff and Volunteers
- Evaluative Research.

A. COMMUNITY OUTREACH

American Red Cross chapters nationwide will serve as the network for training and disseminating information to the community. Chapters will be involved in direct public education activities, such as workshops, public forums, use of the television primer for non-broadcast viewing, and meetings with public policy makers.

More specifically, the AIDS Public Education Program has made contact on a national level with the National School Boards Association, National Governors Association, National Conference of State Legislatures, the U.S. Chamber of Commerce, and the Washington Business Group on Health for the purpose of providing AIDS education and information to ensure a broad outreach effort.

In addition, chapter-developed resources such as workshop materials, handouts, educational materials, and other AIDS-related resources will be used as part of a resource directory that will be shared throughout the Red Cross system to be used for community outreach activities. Additional resources and materials will be developed and distributed nationally, based on the needs of the chapters. In order to generate chapter commitment and involvement, the following activities are being implemented.

Chapter Education/Outreach Packages. These will be developed and distributed on a monthly basis with a specific focus on the AIDS issue. The first package contained materials that address the general facts and issues related to the AIDS epidemic. Subsequent materials will focus on specific target audiences: teenagers and young adults, employers and employees, health care professionals, and civil servants such as police and firefighters. Chapters will be encouraged to set up public forums in the community to establish an ongoing discussion about the disease and its potential impact on the community.

Blood Donor Materials. These materials will be distributed to all Red Cross blood centers around the nation to inform the public about AIDS, with an emphasis on the relationship of AIDS to the blood supply. It will also explain in lay terms the facts about the ELISA and Western Blot blood screening tests that determine the presence of antibodies to the AIDS virus.

Chapter Workshops. The chapters will be encouraged to provide workshops on AIDS for the general public and interested groups within the community, such as schools, church groups, civic organizations, and corporations. Chapters will receive guidance for these workshops, including suggestions for the agenda, speakers, and materials relevant for the meeting. The Red Cross National Headquarters will serve as an information repository and guide for the chapters as they proceed in their outreach activities.

Slide and Tape Shows. A series of four slide/tape shows will be developed and distributed to the chapters. The target audiences of the shows will be teenagers and schools, employers and employees, and health professionals. These slide/tape shows will be used by chapters as the focal point for public forums and workshops. A group leaders' discussion guide will be developed for each slide/tape show.

Teleconferences for Health Care Professionals. In cooperation with PBS television station WQED in Pittsburgh, the AIDS Education Program will sponsor two workshops on AIDS that will link hospitals and health care professionals. These workshops will be teleconferenced to twenty hospital downlink

sites around the country. They will reach a national cross section of individuals in the health care profession including doctors, nurses, support staff, who need to know the facts about AIDS and the latest medical information about necessary precautions for their profession.

B. MASS MEDIA ACTIVITES

Television Primer. Television is a highly effective medium for transmitting information to a broad range of audiences. It is for this reason that the Red Cross has commissioned the production of a 60-minute television show that will serve as the pivotal piece for the educational outreach effort on AIDS. This production will consist of three separate modules linked together to form a comprehensive program for the general public. The Public Broadcasting Service (PBS) is prepared to feed the program to its stations nationwide for rebroadcast at locally determined times. The modular approach gives local television stations the opportunity to fill a normal half-hour program slot with a 20-minute pre-produced module, followed by a local component with a panel of experts drawn from the community. The modules will also be valuable in a variety of non-broadcast settings, such as workshops and forums. The three modules of the television program will address the following content areas:

The Facts. This module will explore the epidemiological background of AIDS to explain how to prevent the spread of the disease. What is known about AIDS? What is the genesis of the AIDS virus? How does it affect the immune system? How is it transmitted? What can the HTLV-III antibody test tell us?

The Individual Response. What do the facts about AIDS mean for the individual? What behaviors put people at risk? How do we protect ourselves and our children? If test results are found to be positive, what should we do? What moral obligations do we have to people with AIDS?

The Community Response. What community responses have proven effective in helping AIDS patients? What can local organizations do to help? What social, economic, legal, and moral issues are raised by the threat and fear of AIDS? How do we resolve the conflict between individual rights and the protection of society? Who should bear the burden of escalating health care costs? How should communities, businesses, and legislative jurisdictions respond? What role must each of us play as responsible citizens?

Promotional Package For Television Primer. The marketing strategy for the television primer is designed to create strong local interest in this AIDS documentary, which will give the American public vital information about AIDS while dispelling misunderstandings and hearsay about the disease.

A two-pronged approach will be taken to market the primer:

- A carrier envelope and pocket folder with the headline "HELP STOP AIDS" will be sent to all of the Red Cross chapters which, in turn, will distribute these promotional pieces to community groups such as the Boy Scouts of America, schools, and health professional organizations in an effort to create an interest for the program. Chapters will set up a telephone information line for community groups to schedule showings of the documentary. Chapter public relations directors will send letters to local television stations and PBS program directors promoting the AIDS documentary. They will also develop a series of news releases to promote the program.
- A brochure and self-mailer will be distributed to inform the general public how to help in the fight against AIDS by "... Spreading Facts Instead of Fears." It will

emphasize the importance of understanding the nature of the virus, and thereby create a demand for the three-part program. This brochure will be designed as a poster so that the recipient agency can post it on a bulletin board to further reinforce the message.

In the second phase of this promotion effort, chapter staff and volunteers will use personal telephone solicitations or meetings with leaders or community groups to explain what the Red Cross chapter has to offer. Slides and photos will be developed and distributed as TV announcements to promote the program. Other announcements will be placed in appropriate newspapers and journals.

As part of the package of materials to accompany the TV primer, the Red Cross will produce an educational brochure, in English and Spanish, for use in the community.

NBC-TV AIDS Project. On January 21, NBC-TV will will broadcast a prime time special television program on AIDS, which will feature prominent medical professionals. Commentator Tom Brokaw will invite viewers who have their own personal questions about AIDS to call their local Red Cross chapters, where physicians will be available for a two-hour period to answer these questions. This activity will take place in 289 cities nationwide that have an NBC affiliate. Chapters will follow up with printed material and other outreach activities as needed.

Red Cross AIDS Radio Project. Plans are under way for Congress to declare the first week in April as National AIDS Education Week. During this week, the Red Cross AIDS Radio Project will provide stations with five 30-minute, in-depth investigative documentaries, produced by radio journalists known for unbiased, authoritative reporting. They will conduct interviews with the nation's leading experts on AIDS and present this material in a lively and non-academic manner. These programs will be followed in many areas by live call-in shows, during which listeners will be able to question medical and public health experts.

The Radio Project will culminate on Saturday of that week when local stations will be linked via satellite for a four-hour, coast-to-coast National Town Meeting on AIDS Policy, which has the potential to reach millions of citizens. Each hour will feature a panel including the nation's leading scientists, health officials, and policy makers, and will be hosted by trusted public figures. Listeners from around the country will be able to call in, ask questions, and join the discussion.

This week of programming will be provided free to thousands of radio stations across the United States. A telephone survey of selected stations, including WNYC-AM (NYC), WBEZ-FM (Chicago), Vermont Public Radio, WMFE-FM (Lexington, KY.), and KPFK-FM (Los Angeles) indicates that stations large and small are very enthusiastic about carrying the program. Discussions are now under way with ABC Talk Radio and with networks in Canada (CBC), Australia (ABC), and Great Britain (BBC) to carry the radio broadcast. The promotional package for the Radio Project will use the same themes as those for the television primer, to further unify media outreach efforts.

After the radio broadcast, these programs will be available on cassette for use by Red Cross chapters with community groups, business leaders, health care centers, schools, and libraries. This radio series will form part of the basic materials used in community outreach activities by the Red Cross to educate the general public about AIDS.

Public Service Announcements. The Red Cross is producing four 30-second PSAs in conjunction with the U.S. Public Health Service. Two of these informational spots, designed to allay unreasonable fears and help prevent the spread of AIDS, are targeted for mid-January release to the networks. The other two are scheduled for spring release. Radio lifts will be developed in English and Spanish from these four spots.

These 30-second PSAs bring four important messages to the public:

- You can't get AIDS from donating blood. Healthy people are needed to donate and keep the blood supply safe.
- The AIDS virus is spread by sharing IV needles. Help stop the spread of AIDS by controlling drug-related activities.
- AIDS is not spread by casual contact. Call the Public Health Service AIDS Hotline for accurate information on transmission.
- Get the facts about AIDS. Call the Public Health Service AIDS Hotline.

These spots are suitable for all audiences. Rock singer Patti Labelle will do a spot on dispelling rumors about AIDS that will be particularly appropriate for airing in teen programming featuring music videos. Collateral materials being developed as part of this PSA campaign include radio "lifts" in English and Spanish and posters.

Media Seminars. The Red Cross will hold three regional seminars to educate reporters and broadcast journalists facts about AIDS

The first seminar will be held on the East Coast; the second, at the Annual Convention in Indianapolis; and the third on the West Coast.

MacNeil-Lehrer Production. The producers of the MacNeil-Lehrer News Hour have offered the Red Cross the possibility of producing a two-hour special program on AIDS in fall 1986. The Red Cross will commission a feasibility study of producing such a program.

Advertising Council Campaign. Through its volunteer advertising agency, J. Walter Thompson, and the Advertising Council Inc., the Red Cross has the opportunity to produce a major national public service advertising (PSA) campaign on AIDS. The Red Cross intends to direct the new campaign toward teenagers and young adults who are in critical need of information about AIDS. High school students are at an age where they respond to peer group pressure and being a part of the group is very important. An underlying theme of this campaign will be to dissuade the young adult population from drug use and causal experimentation with sex. These ads will inform them about the dangers of such activities and underscore their option to "Say No!" Discussions of the feasibility of such a campaign will begin in January with the advertising agency.

C. TRAINING FOR RED CROSS STAFF AND VOLUNTEERS

The community outreach and public education effort builds on the strength of the national Red Cross network. Therefore, it has been important to train a central core of staff and volunteers who can address the many issues related to AIDS raised by individuals in the community. A general information letter that details the AIDS Public Education Program has been distributed throughout the Red Cross system. Chapters and Blood Centers were asked to identify a lead staff person to serve as the contact for all AIDS program activities. Through the use of local and regional workshops and possibly teleconferencing, designated chapter staff will have the opportunity to learn about the disease, establish linkages to other local AIDS networks in their communities, and determine their local medical and service needs to better organize resources for their community.

Initial surveys and contacts with over 40 chapters indicate that initial concern focused on the safety of the blood supply. With the introduction of HTLV-III antibody testing, attention has now focused on the fears of personal risk of contracting the dreaded disease.

Chapter Needs Assessment. This document will be used to identify the individual chapter needs, determine the present level of chapter activities in the area of AIDS public education, and provide the chapter with some basic tools for identifying the AIDS resources, programs,and activities within their local community.

Chapter Information Package. These packages will be produced and disseminated on a frequent basis to keep the chapter staff up-to-date on the most recent facts about AIDS and strengthen the chapter network. They will include reprints of recent CDC guidelines, policy statements from public officials, fact sheets, internal Red Cross policy statements, and news about the Red Cross program.

Media Package. These packages will be produced and sent to chapter public relations directors on a quarterly basis.

The purpose is to keep the chapters informed of the Red Cross education effort so they can respond to media questions about AIDS and ongoing AIDS-related educational activities in the community.

Chapter Training Sessions. A series of chapter training sessions will be conducted in conjunction with the regional meetings of the Red Cross chapters. These meetings will provide an opportunity for a wide cross section of chapter staff and volunteers to learn more about the AIDS epidemic and what they can do in their communities to foster the Red Cross public education effort. Experts will discuss the facts about AIDS and the options open to facilitate discussion that may ultimately influence public policy decisions made within their respective communities. A presentation of AIDS education programs being conducted by chapters in the East, South, Midwest, and Western regions will be held at the Red Cross Annual Convention in June 1986. Several thousand staff and volunteers are expected to attend this session.

National Resource Data Bank. A Resource Data Bank will be established that will contain the most up-to-date information about AIDS and chapter activities. The first data bank is a listing of print and non-print media materials available both in and outside the Red Cross system. Included in the listing will be workshop agendas and handout materials, videotapes, reference papers, and other resources. At the present time, materials have been identified from 10 chapters and are entered in the computer system. This information can be selectively searched and information provided to chapters on request. The second data bank will contain an annotated list of national programs and persons who can serve as resources in providing AIDS programs and information. All of the resources will be accessible by content area and population served.

D. EVALUATIVE RESEARCH ACTIVITIES

Nationwide Evaluation. The Red Cross will conduct a comprehensive evaluation of the Community Outreach effort to assure the effectiveness of these activities. A stratified sample of ten chapters will be selected for a formative evaluation to assess and improve the effectiveness of the ongoing program. More specifically, six chapters will be selected from the high risk communities and four will be selected from low risk communities. The sample will be geographically representative of the Red Cross nationwide chapter network. The evaluation will focus on the program participants, process, and outcomes.

Basic demographic data will be collected about individual participants to determine how many individuals participated in the program, and who they were in terms of age, race, sex, and years of education.

Program process refers to the character of the program intervention and the steps it takes to implement the various activities. Every effort will be made to ensure that the outreach effort reaches the widest possible audience across the nation.

Documentation of process serves several purposes. A description of how a project was actually implemented assists other chapters and organizations who seek to replicate the program activities. It will enable the Red Cross to determine the degree of effectiveness of particular activities given the variation among chapters and communities within the nationwide Red Cross network.

Pre Test Materials. All materials will be pretested before they are produced in final form. This is of critical importance given the nature of the material to be produced. Every effort will be made to ensure the accuracy of content and appropriateness of the materials for the targetted audiences, such as schools, workplace, and health professionals.

Community Evaluation Kit. This community programming evaluation tool will enable the chapters to evaluate the effectiveness of their outreach activities and determine the lacunae in their outreach efforts. It will also provide valuable information for the National Headquarters to determine what does and doesn't works for the chapters. This allows for continual "fine tuning" of materials and activities for community outreach.

Evaluative Focus Groups. Each of the four Public Service Announcements will be tested to determine its effectiveness with the general public. A series of focus groups are scheduled in selected community sites to get feedback and make changes, where necessary, to maximize the effectiveness of the PSAs in educating the general public about AIDS.

E. DESCRIPTION OF APPLICANT ORGANIZATION

The American Red Cross is in a unique position to undertake a comprehensive program to educate the general public about the AIDS epidemic. One of the primary corporate objectives of the Red Cross is to provide educational outreach services to the community through its national chapter network. The organization has a long history of involving the public in its programs and services, and is committed to health promotion and the adoption of healthy lifestyles for the general population. The Red Cross also has a national training network that potentially can reach every community in the nation. This AIDS Public Education Program will build on the organization's existing programs while providing training to interested members of the community and developing materials for dissemination to a wide cross section of community organizations. The Red Cross has a history of responding decisively to the problem of AIDS and blood transfusion.

The following section provides information on the Red Cross ability to conduct a demonstration project and provide rigorous evaluation of the education program and outreach activities.

Overall Organization Services and Decision-Making Practices

The American Red Cross is a multipurpose voluntary health and social welfare organization. It provides human services in the United States through approximately 3,000 chapters and 57 regional blood centers, and worldwide through approximately 300 field stations on military installations. Membership in the American Red Cross is open to all people in the United States and its territories and dependencies.

Among the missions of the Red Cross are the improvement of the quality of human life and enhancement of individual self-reliance and concern for others. The Red Cross helps people avoid, prepare for, and cope with emergencies through services that are governed and directed by volunteers. These services are consistent with the congressional-charter and the internationalist principles of the Red Cross.

To accomplish its aims, the Red Cross maintains a system of local, national, and international disaster preparedness and relief; provides voluntary blood services to a large segment of the American people; helps individuals acquire the knowledge, skills, and attitudes for a safe and healthy lifestyle through a wide array of health and safety programs and services; provides educational opportunities and volunteer experience for youth; serves as an independent medium of voluntary relief and communication between the American people and their Armed Forces; and assists the government of the United States in meeting humanitarian treaty commitments.

The Red Cross is governed by a 50-person Board of Governors. Eight members of the Board are appointed by the President of the United States, 30 are elected by chapters at the national convention, and 12 are elected by the Board of Governors as members-at-large.

The National Headquarters of the Red Cross, located in Washington, D.C., and three Operations Headquarters, located in Alexandria, Virginia; St. Louis, Missouri; and Burlingame, California, provide administrative and program support for chapters.

Each Red Cross chapter, regardless of its size, has a chairperson and a board of directors. Chapters are responsible for meeting their charter obligations to assist service members, veterans, and their families, and to carry on disaster preparedness and relief activities. Beyond these two services, many chapters provide a wide array of health promotion and disease prevention programs. These programs and services are delivered by both volunteer and paid staff. Some chapters are staffed entirely by volunteers. In 1984, Red Cross chapters nationwide issued more than 6 million certificates in first aid, CPR, Preparation for Parenthood, nutrition, and other health related courses.

Chapters serve their communities with the help of financial resources and volunteers provided by the community. The major source of program funds is through local United Ways and federated fund-raising campaigns. Additional funds are provided through community contributions, grants, and cost-sharing arrangements. Start-up grants for some programs are provided by local foundations, government agencies, and businesses. Most course participants are charged a fee for instructional program materials.

Volunteers--more than 1.7 million of them--play a major role in Red Cross chapters. They provide program leadership for chapters, make policy decisions, and serve the community. To perform these activities, they are trained to sharpen their skills and prepare them for positions of increasing responsibility in providing and directing Red Cross services.

(ATTACHMENT A)

AIDS PUBLIC EDUCATION PROGRAM

Oversight Committee

Chair:
Mr. Wallace Jorgenson
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Jefferson-Pilot Broadcast
One Julian Price Place
Charlotte, North Carolina 28208

Co-Chair:
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President
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Dr. Frank Stanton, PhD.
Former National Chairman
American Red Cross
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New York, New York 10022-8184

(ATTACHMENT B)

RED CROSS CHAPTER MATERIALS
MEDIA RESOURCE FILE

CHAPTER	DESCRIPTION
District of Columbia Chapter	AIDS: A Workshop for Health Care Professionals - Agenda and speakers' list for a one day workshop (12/85)
District of Columbia Chapter	Questions and Answers About American Red Cross Use of the HTLV-III Antibody Test - a 2-1/2 page fact sheet (10/85)
Seattle Chapter	Living with AIDS - 58 min. teaching tape on AIDS (85)
Greater New York Chapter	AIDS: Fighting the Battle with Education & Services - agenda and handout materials for a two-day workshop (12/85)
District of Columbia Chapter	A Message About AIDS from the American Red Cross - leaflet for blood canteen and as a pay envelope stuffer (10/85)
Rochester/Monroe County Chapter	AIDS Protocol - Minimum Guidelines for Care in the Home - 3-page guidelines (11/85)
Rochester/Monroe County Chapter	AIDS: An Update for the Community - agenda and content outline for an evening community presentation
Greater New York Chapter	AIDS: HTLV-III - 1-page brochure on HTLV-III for blood donors and general public
Greater New York Chapter	Home Nursing Course for AIDS Care Givers - 70-page instructors' guide for a six-session course to be used with the ARC Home Nursing Instructors' Guide (1983)
Greater New York Blood Program	Information for Donors with HTLV-III Antibodies - counseling videotape, approx. 10 min.
Greater New York Blood Program	Information for Donors with HTLV-III Antibodies - script for

	videotape
Los Angeles-Orange County Blood Services	AIDS: Answers to Blood Donors' Questions - leaflet for blood donors (8/83)
Greater New York Blood Program	What You Should Know About AIDS - leaflet for blood donors (8/83)
Greater New York Blood Program	Q & A - leaflet for donors (4/85)
Atlanta Region Blood Services	AIDS Fact Sheet - 2 page fact sheet for blood donors and general public (8/85)
Atlanta Region Blood Services	FYI - AIDS Information package, 11 pages (7/85) - general public and blood donors
Missouri/Illinois Blood Services	AIDS Presentation Outline - 6-page workshop outline for health workers (10/85)
Missouri/Illinois Blood Services	AIDS Presentatioon - script for a tape slide presentation on AIDS; 17 pages (9/85)
Mid-America Blood Servicees 20 min.	AIDS: Tracking the Mystery - videotape - general public
Mid-America Blood Services	AIDS - 24-page script for a tape/slide presentation to technical audiences
Mid-America Blood Services	AIDS is a Serious Condition Characterized by a Specific Defect in Natural Immunity Against Disease - 33-page script for a tape/slide presentation to interdisciplinary audience (10/85)
Hawkeye Chapter (Waterloo)	AIDS Education Program - 2 hr community workshop - print materials include: community leader letter, facilitator materials, audience brochure; media a 15 min videotape (12/85)
Hawkeye Chapter (Waterloo)	Panel Presentation on AIDS - 15 min videotape for community use alone or with workshop materials above (12/85)

American Red Cross

National Headquarters
Washington, DC 20006

AIDS PUBLIC EDUCATION PROGRAM
Estimated Cost of Activities

COMMUNITY OUTREACH:

Community Education/Outreach Packages (6) and Community Resource Kit	$ 10,200
Blood Donor Public Service Announcements and Collateral Materials	$ 10,400
Slide/Tape Programs (4) and Discussion Guides	$ 53,200
Educational Brochure (1 million copies) in English and Spanish	$ 41,000
Health Professionals Teleconference and Collateral Materials	$ 85,000

SUBTOTAL: $ 489,800*

MASS MEDIA ACTIVITIES:

Television Primer Promotional Materials and Distribution (1,000 videos, 400 prints)	$580,000*
National Public Radio Project Promotional Materials & Cassette Tapes (1,000)	$ 80,500
Public Service Announcements (4) English and Spanish Radio Spots Posters	$ 40,000
Regional Media Seminars (3)	$ 24,000
Advertising Council Campaign	$300,000
MacNeil-Lehrer Television Program Feasibility Study	$ 5,000

SUBTOTAL: $ 739,500*

*To maximize cost efficiency and usage, Television Primer will be used in Community Outreach and Mass Media Activities. Cost is divided, adding $290,000 to each category.

Estimated Cost of Activities--Page 2

TRAINING:

Chapter Training	$ 21,200
SUBTOTAL:	$ 21,200

RESEARCH:

Evaluation Research	$200,000
SUBTOTAL:	$ 200,000

TOTAL ESTIMATED COST: $1,450,500

ESTIMATED COST OF PROPOSED 1986-1987 ACTIVITY:

MacNeil-Lehrer Television Program and Promotional Materials	$1,000,000

3) Question:

Does PHS believe that private sector programs in effect offset its own, i.e., that a $17 million private initiative permits PHS to reduce its commitment by a similar amount; or does PHS intend to encourage private efforts by augmenting them with its own funds?

Answer:

Private sector initiatives for public information are geared to local areas. Except for the American Red Cross we know of no major national efforts by the private sector for educating the public about AIDS. We plan to support organizations, such as we have done with the American Medical Association (see #4 below), to develop educational materials that can serve as prototypes for local communities to use in developing their own information/ education materials.

In FY '87, we plan to support demonstration projects consisting of public affairs campaigns at the local level to inform the public about about AIDS, evaluation of these campaigns, and workshops to pass on the knowledge gained from them to other communities.

Question:

4) If so, what collaboration exists?

Answer:

PHS is encouraging the private sector to develop information/education programs by providing financial support in needed areas. For example, we are working with the American College Health Association to develop risk reduction materials for students on college campuses, and we will be working with other educational groups as well, including the National Education Association, the American Federation of Teachers, the National Parent-Teachers Association, and the American School Health Association.

We are now providing support to the American Medical Association to educate physicians about AIDS and develop a speakers bureau, which will fill a great need of communities to have their own experts talk to local groups and respond to media inquiries about AIDS. A pilot program is being developed for four high-incidence states and will be expanded to the remaining 46 states.

5) Question:

What are your efforts to coordinate with the private sector on a comprehensive basis?

Answer:

The Public Health Service is working to establish a national coalition to coordinate and maximize public and private sector communications activites to inform and educate all segments of the public about AIDS. A coalition would serve to identify areas of need in public education and to minimize duplication of efforts. The first meeting of such a group will be held this summer. In addition, through the coalition, we will sponsor the first national conference on AIDS communications to enlist new participants, strengthen the existing liaison, and plan future efforts.

6. Question. Are states and localities really capable currently of conducting sophisticated AIDS public education and prevention programs?

Answer. Quality local talent exists in both government and volunteer and other-supported special interest groups. The key is to be able to draw these together, and stimulate them to focus on the AIDS problem. Funding through the capacity-building grants is intended to help the States in their internal assessment, planning and program implementation at a variety of levels. These funds as well as those provided through the augmentation awards can also help States secure any additional talented, dedicated personnel they may need.

7. Question. How much federal money is allocated to such programs?

Answer. Approximately $31.5 million has been allocated to support State and local AIDS public education and prevention programs in FY 1986.

8. Question. Who oversees the effectiveness?

Answer. In the Program Announcement for all health education/risk reduction programs, CDC required that applicants clearly describe planned evaluation methodologies. These will be implemented by funded programs and used to monitor effectiveness. In addition, CDC will be providing close technical support to the States to assist their management staffs in developing a core capacity for Statewide health education/risk reduction programs. CDC will also be offering training to provide State managers with the skills and knowledge necessary to facilitate the organized collaboration of community level resources, and to plan and implement this program. Lastly, CDC will be collaborating with each area to prepare and implement methods for evaluation of the effectiveness of these AIDS health education programs.

9. Question. Where are reports?

Answer. Four Community-Based Demonstration Projects for AIDS Prevention and Risk Reduction were awarded in late September 1985. Progress reports from these projects should be received shortly. The remaining CDC-funded projects have either been awarded within the past few weeks or have not yet been awarded. Therefore, no reports have yet been received.

10. Question. At roughly $115,000 per grant, are CDC's 1986 capacity-building grants to facilitate this expertise really sufficient to address the need, particularly in areas where incidence of disease is low and transmission could conceivably be slowed or stopped?

Answer. The purpose of capacity-building grants is to help the States appraise their AIDS health education needs and develop the capacity to deliver health education/risk reduction programs. The ability of each State to accomplish this initial assessment planning, and then program implementation, will depend more on quality management and organization than on large levels of funding. While the funding is a necessary stimulus, the key is to draw together the impressive array of voluntary and otherwise supported resources concerned with AIDS available in each community. These funds can also help States secure the talented, dedicated personnel needed to bring all available resources to bear on the AIDS problem. Therefore, CDC believes that the amount of funds awarded is less important at this point than how effectively the States put them to use. This is true whether the incidence is high or low.

In coming months, CDC will be providing close technical support to the States to assist their management staffs in developing a core capacity for Statewide health education/risk reduction programs. Beginning in April, CDC also offered training to provide State managers with the skills and knowledge necessary to facilitate the organized collaboration of community level resources, and to plan, implement, and evaluate an effective AIDS health education program.

11. Question. What should be done differently?

Answer. With regard to our existing efforts we believe that all reasonable actions are being taken. More time will be necessary to assess the current approach since projects are only just gearing up, and evaluation strategies are still in the planning stages.

12. Question. Is it just a function of more money or must there be a better coordinated effort?

Answer. The ability of each state to accomplish this initial assessment planning and then program implementation will depend more on quality management and cooperative organization than on large levels of funding. The key is better cooperative efforts among the numerous groups currently active in AIDS prevention and control. Therefore, CDC believes that the amount of funds awarded is less important at this point than how effectively the States put them to use.

13. Question. To support capacity-building grants, what does CDC propose to provide states and localities in the way of technology transfer of materials and expertise?

Answer. CDC will use three methods of providing technology transfer and expertise to support capacity-building. First, CDC staff will be providing on-site technical assistance to review proposed procedures, identify common operational problems, and facilitate an exchange of ideas about workable approaches and techniques. CDC will document these problems and viable solutions and make this information available to all cooperative agreement areas through periodic communiques and follow-up technical assistance visits. Second, CDC will carefully review program narrative reports from cooperative agreement areas and disseminate ideas and technology that would be useful for all to consider. Third, among the key responsibilities of the several Community-Based Demonstration Projects for AIDS Prevention and Risk Reduction is the need to test new approaches and thoroughly document all activities. These areas will then participate with CDC staff in efforts, such as training, to assure all other AIDS health education/risk reduction cooperative agreement areas are able to rapidly implement the best available technology with a minimum of wasted effort.

14. Question. Is this technical assistance to be paid for out of grants budgets or other sources?

Answer. All technical assistance will be supported from CDC program operations funds for AIDS.

15. Question. What is the total estimated cost of technical assistance?

Answer. The total estimated cost of supporting and performing technical assistance to be provided by CDC is approximately $1 million.

16. Question. Could AIDS education and prevention be handled more effectively by regional centers rather than centrally at CDC?

Answer. There are three reasons why we believe that AIDS education and prevention are better handled at CDC rather than through regional centers. First, the AIDS education and prevention program authorized by Congress focuses on operations and service delivery rather than research. CDC has the capability of managing both types of programs, but has particular expertise in the former type of program. Transferring the technology and expertise for this to regional centers would require duplication of this expertise at each site. Second, the AIDS prevention and education programs are to be implemented through grants to State and local health departments with whom CDC has an effective and long standing relations. Third, the field of AIDS is changing technologically and strategically at such a rapid pace that centralized management is imperative to facilitate rapid adjustments down to the service delivery level. The ability to effect such changes in a timely and uniform manner would not be improved by adding a regional layer.

17. Question. Would it make more sense to transfer technology and expertise to, say, six regional centers (such as the Centers for Interdisciplinary Research on Immune Disorders, which are already directed to conduct education) which could tailor substance and programs for their particular regions?

Answer. There are three reasons why it is felt that AIDS education and prevention are better handled at CDC rather than through regional centers. First, the AIDS education and prevention program authorized by Congress focuses on operations and service delivery rather than research. CDC has the capability of managing both types of programs, but has particular expertise in the former type of program. Transferring the technology and expertise for this to regional centers would require duplication of this expertise at each site. Second, the AIDS prevention and education programs are to be implemented through grants to State and local health departments with whom CDC has an effective and long standing relations. Third, the field of AIDS is changing technologically and strategically at such a rapid pace that centralized management is imperative to facilitate rapid adjustments down to the service delivery level. The ability to effect such changes in a timely and uniform manner would not be improved by adding a regional layer.

18) Question:

Do we need need a central "AIDS Information Clearinghouse," on the order of those already in existence for cancer and other diseases, to coordinate and distribute AIDS education and prevention expertise?

Answer:

An "AIDS Information Clearinghouse" is an appealing concept. However, it would be costly to operate and care would have to be taken not to duplicate the efforts of many State and local governmental agencies and private organizations disseminating AIDS-related information in various ways. In addition, it would have to be coordinated with the efforts of several national agencies, for example the United States Conference of Mayors, which publishes a periodic newsletter informing mayors and other local officials about developments in AIDS research and program activities.

19) Question:

If so why has this not been done before?

Answer:

With the ongoing efforts, we have not felt the need for a clearinghouse. This summer we plan the formation of an AIDS coordinating council as mentioned in an earlier answer.

20) Question:

How much would such a clearinghouse cost?

Answer:

CDC estimates that a central "AIDS Information Clearinghouse," developed to meet the information needs of researchers, academicians, private health care practitioners, publich health personnel, and governmental officials concerned with AIDS, plus the general public, would cost a minimum of $3 million annually.

21) Question:

Who would operate it (a central "AIDS Information Clearinghouse")?

Answer:

An AIDS clearinghouse operation of the magnitude needed to respond to all of the likely needs for information on this subject would require space and personnel well beyond the current funding and FTE resources of CDC and the other agencies within PHS. Even if funds were available, such a clearinghouse would best be managed through a cooperative agreement or contract with an appropriate outside vendor.

22. Question. Why is the majority of AIDS education funding being made available only through state and local public health authorities?

Answer. AIDS is a public health problem which legally falls within the purview of the official health agencies in each State and locality. Under statute and regulation, such agencies have well defined responsibilities for the control of communicable disease within their respective jurisdications. Therefore, while many public and private community groups and organizations have an interest and some experience in dealing with various facets of the AIDS problem, CDC believes that the coordination and augmentation of their efforts as part of CDC funded programs should be the responsibility of the health department.

CDC also believes that the official health agencies are in the very best position to balance all of the different interests and viewpoints of various organizations, help to coordinate and focus their energies, and augment their efforts for an effective overall community-based programs of AIDS health education and risk reduction. CDC further believes that private sector institutions which can contribute to the overall AIDS control effort in a particular community will make their interest known, but that decisions regarding local roles and resource allocations are best made by the official health agency which can most objectively make those judgements.

23. Question. Because so many of those authorities are not up-to-speed on AIDS, are they able to spend funds wisely and effectively?

Answer. With increased funding, technical assistance from CDC, and technology transfer areas (particularly with a low incidence of AIDS) should rapidly become up-to-date on AIDS prevention and control strategies. Part of CDC's activities will be to evaluate these efforts. Areas with a high prevalence of AIDS are already state-of-the art, and in fact provide models from which all of us can learn.

24. Question. Who oversees these efforts?

Answer. CDC is overseeing these efforts and plans to assess them through the development of core evaluation strategies which are currently being developed.

25. Question. Where are the reports to date? Please send them to the committee.

Answer. Because the Community-Based Demonstration Projects for AIDS Prevention and Risk Reduction, the areas in which the prototype evaluation strategies are first being developed and implemented, were so recently begun, no actual evaluation is yet underway.

26. Question. Wouldn't it make sense to make much more funding available to any institution, including those in the private sector, capable of demonstrating the ability to carry out effective programs?

Answer. CDC believes that the official health agencies are in the very best position to balance all of the different interests and viewpoints of various organizations, help to coordinate and focus their energies, and augment their efforts for an effective overall community-based program of AIDS health education and risk reduction. CDC further believes that private sector institutions which can contribute to the overall AIDS control effort in a particular community will make their interest known, but that decisions regarding local roles and resource allocations are best made by the official health agency which can most objectively make those judgments.

27. Question. How long does it take to process grants?

Answer. The first step in processing grants is to publish a Program Announcement in the Federal Register. Applicants usually have between 30 and 45 days to respond with applications. These applications are then subject to peer reviews and objective panel reviews, followed by recommendations by the appropriate program official to the grants management official. Negotiations then take place with the potential grantee, and awards are finally made. This process usually takes approximately 3 to 4 months from the date that a Program Announcement is published in the Federal Register, although other concerns such as the need to obtain Human Subjects clearance, may increase the time needed.

28. Question. Is there a backlog?

Answer. There is currently no backlog.

29. Question. How long is the backlog?

Answer. There is currently no backlog.

Question #30:

Concerns have been raised that AIDS may be transmitted by dental equipment. Has there been any documentation of spread of the AIDS virus by dental equipment? Is the FDA considering regulation of dental equipment under the medical device regulations?

Response:

The FDA's Center for Devices and Radiological Health (CDRH) has been closely examining the issue of a potential link between possible aspiration of oral fluid intc dental equipment and the transmission of AIDS. Through discussions with the Centers for Disease Control, CDRH staff have confirmed that there is no epidemiologic evidence of illness resulting from this operational aspect of dental units. It should also be noted that there has been no instance of transmission of AIDS in the dental setting. In fact, there have been no documented cases of AIDS transmitted through means other than sexual contact or intravenous drug use of blood transfusion.

Independent of the AIDS issue, dental equipment is subject to FDA regulation under the aegis of the 1976 Medical Device Amendments to the FDC Act. This means that dental instrument manufacturers must comply with the Act's requirements, such as product labeling, registration and listing, and good manufacturing practices. Although there is no current evidence regarding the transmission of AIDS or any other human illnesses via dental equipment, we believe that certain precautionary measures still should be pursued. To this end, the CDRH is sending a letter to all dental equipment manufacturers to suggest that existing labeling be revised to inform dentists and ancillary personnel of the need to run the equipment between patients in order to expel saliva that might have been aspirated into the handpiece. This labeling change is in accordance with the recently published guidelines by CDC for infection control in dentistry. The CDRH also plans to meet with dental equipment manufacturers the week of May 13 to discuss this issue in more detail.

Question 31:

I would appreciate your comments about a problem of AIDS reporting brought to my attention by the Washington Area Council on Alcoholism and Drug Abuse. The Council feels that the current reporting system obscures relevant data on the spread of AIDS and the relationship of AIDS within the substance abuse community.

One of the statistical representations that the Council finds particularly problematic is the "Weekly Surveillance Report" of the Center for Disease Control. Item #4 of that report is entitled "Patient Groups." The groups are ordered hierarchially; cases with multiple characteristics are tabulated only in the group listed first. Thus the presentation of intravenous (IV) drug users appears to be 17% of the total population diagnosed with AIDS, and not 25% which is the accurate number. The other 8% is hidden under the label of homesexual.

Within the CDC report there appear to be no indicators for alcohol and substance abuse for the 75% who are not IV users. The Council feels that to maintain the current hierarchical system appears to serve little value beyond perpetuating misinformation on the multi-cultural dynamics of persons under discussion. As well as to encourage more prejudicial responses to a growing health crisis.

Response:

As this question points out, earlier reports by the CDC did list risk groups for AIDS in a hierarchical fashion. Discussions between CDC and the National Institute on Drug Abuse have led recently to the reporting of risk groups by multiple classifications, acknowledging the 8% overlap between homosexual/bisexual and intravenous drug users classifications. We believe that this situation has been adequately resolved.

Question 32:

Mrs. Kushnick has testified at this hearing that perhaps as many as 80% of the pediatric AIDS patients are abandoned children. In addition, she has stated that abandoned AIDS children number in the hundreds. These children apparently live in the hospital unvisited by even their parents. What do you know of this problem. If there is a problem, what is being done?

Response:

Pediatric AIDS surveillance information reported to CDC does not include information on whether children are abandoned, but many children infected with the virus have need for foster care due to parental death (e.g., from AIDS) or unavailability. More specific data on this question could possibly be provided by child protection agencies in New York City, Miami, and Newark. Current surveillance data indicate that 173 of the 289 children reported to CDC to have AIDS are known to have died. Although a firm estimate of the number of children infected with HTLV-III/LAV cannot now be made, it is thought that there are at least several hundred more with AIDS-related illness or a symptomatic infection than have been reported with AIDS.

Question 33:

Mrs. Kushnick has testified that the CDC response to the pediatric AIDS problem was slow and that the CDC is now overwhelmed by the problem. What is your response to this allegation?

Response:

The first suspected pediatric AIDS case was reported to CDC in November 1982. CDC reported the occurrence of pediatric AIDS, including the first blood transfusion-associated case, in the Morbidity and Mortality Weekly Report (MMWR) of December 10 and 17, 1982. Subsequently, a pediatric case definition for AIDS was developed and published. Based on additional epidemologic information, the case definition has since been refined. Guidelines for preventing perinatal transmission of HTLV-III/LAV infection, as well as guidelines for preventing infection in adults, infants, and children, have been published in the MMWR. CDC has initiated a study of the outcome of pregnancies complicated by HTLV-III/LAV infection.

QUESTIONS FOR DR. MacDONALD FROM SENATOR KENNEDY

1. Question. Is it correct that all the AIDS research funding for fiscal year 1987 is being placed in the Office of the Assistant Secretary for Health?

Answer. In fiscal year 1987, the Department has proposed centralizing funding for AIDS (excluding the Food and Drug Administration) directly into the Office of the Assistant Secretary for Health. This will combine the AIDS funds previously appropriated for Centers for Disease Control; the Alcohol, Drug Abuse and Mental Health Administration; and the National Institutes of Health in a single account. FDA, as part of the Agricultural Appropriation, was not considered for the centralized account.

2. Question. Does this include funds that have been shifted into AIDS research from other areas over the past several years?

Answer. No. The proposal, if approved by Congress, would become effective in fiscal year 1987.

3. Question. Does it also include continuation costs for the new AIDS initiative funds provided in fiscal year 1986?

Answer. Yes. PHS will continue to provide support to those AIDS activities established in fiscal year 1986 and currently plan to continue to provide support to those research activities in fiscal year 1987.

Question 4: What effect is this having on normal activities of other entities such as the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the other Institutes?

Response: The proposal to centralize all AIDS research funding in the Office of the Assistant Secretary for Health has not yet been implemented. Therefore, it is not having any effect on normal activities at this time.

Question 5: What effect has it had on research funded by the Institutes?

Response: Since the proposed centralization has not yet been implemented, there has not been any impact.

Question 6: What percentage of the NCI and the NIAID budgets have in effect been redirected to your office?

Response: The amounts currently anticipated for reimbursement to NCI of $47.2 million and NIAID of $67.5 million would represent 4 and 17 percent, respectively, of the Institutes' budgets in FY 1987.

Question 7: Might it not be better if AIDS research funds were appropriated directly to the Institutes performing the research?

Response: The Department believes that the consolidation of AIDS funding in OASH would result in greater visibility of the AIDS program, would provide broad flexibility to respond to needs when and where they occur, and would facilitate control over funding during a time of overall fiscal restraint.

Question 8: Does this mean that your office controls the contracts, hiring and research of NCI, NIAID and other Institutes?

Response: The OASH will determine AIDS research priorities and will allocate funds to the appropriate PHS components in accordance with those priorities. The degree of control for hiring staff and negotiating and awarding contracts will remain with the individual components.

9. Question. How much of the $234.4 million which was appropriated for AIDS has been sequestered?

Answer. The total amount sequestered was $10.1 million.

10. Question. So, that leaves $224. How much of that amount has the Administration earmarked for reduction by rescissions?

Answer. The Administration has proposed rescissions totaling $41.1 million.

11. Question. If Congress does not approve the rescissions, when will the funds be available?

Answer. If the rescissions are not approved, the funds would become available on April 16, 1986. The PHS would obligate the funds before September 30, 1986.

Question. What projects are awaiting these funds which will be started when they are available?

Answer. PHS will publish a notice of availability of $15 million in funds for AIDS service demonstration projects to solicit proposals from the four MSAs of highest concentration of those affected by AIDS to establish four demonstration projects. We would allow for the receipt of more than one application for consideration from each of the four MSAs. However, each MSA would receive a single grant. Greatest consideration would be given to those applicants who 1) demonstrate a model that provides for a consortium approach to providing a continuum of services to AIDS patients that includes State/local health departments, clinics, hospitals, HMOs, and other community facilities; and 2) give consideration in their approach to contiguous areas (i.e., outside the MSA) with highest concentration of AIDS victims such as Belle Glade, Florida and Newark, New Jersey. In addition, greater consideration will be given to those applicants who demonstrate the greatest degree of coordination and support of local government and demonstrate involvement of appropriate community organizations concerned with AIDS patients.

The proposed grantees would be required to design a community-oriented system of care for AIDS patients which covers a continuum of care from diagnosis to chronic care.

Factors that will be considered in determining the specific allocation to each grantee include comprehensiveness of proposal, size of AIDS population and consideration given to special populations.

The $11.8 million for CDC and the $13.9 million for NIH, not approved by Congress for rescission, will be used to expand ongoing AIDS activities in 1986.

QUESTIONS FOR THE FOOD & DRUG ADMINISTRATION FROM SENATOR KENNEDY

Question 1: Commissioner Young, I think everyone agrees that the development of an AIDS vaccine is a very high priority. What is the status of such development?

Response: The development of a vaccine is a very high priority with the organizations responsible for conducting and supporting research on AIDS. The status of vaccine development against AIDS shows promising results in a number of areas which are being explored. Although nonpathogenic variants of HTLV-III, or killed virus, are not seriouly considered at this time because of potentially negative long-term effects, special genetically engineered, deletion variants which do not kill T cells are now available, as are significant amounts of native virus. Collaborative studies have been initiated by NCI with a number of groups with expertise in infectious recombinant virus research, such as vaccinia, adenovirus, and herpes virus as carrier strains for HTLV-III gene co-expression. If effective, this latter approach may shorten time needed for the more conventional vaccine attempts.

The foremost of the standard approaches used by the NCI is a safe subunit vaccine preparation consisting of one or more purified viral proteins. Based on other retrovirus models, the major external viral coat glycoprotein (gp120) of HTLV-III is expected to contain the epitopes which will elicit neutralizing and protective antibodies. The natural gp120 was considered for the initial learning process because of its molecular complexity. Inoculation of the gp120 into a number of species including rhesus monkeys resulted in the formation of antibodies which not only precipitated the virus but also formed virus neutralizing and cytotoxic antibodies. This means that the antibody was not only capable of killing the virus and that the virus-producing cells could also be killed. The early antibodies were type-specific but could not inactivate less related HTLV-III variants. Because the subunit vaccine preparation showed no toxicity in lower monkeys, the preparations can now be inoculated into chimpanzees. If analogous neutralizing antibodies are induced, then a protection experiment can be tried to see whether primary infection can be prevented in this species. Many questions remain unanswered in the areas of virus types, cross neutralization, and viral pathogenesis. Although enough native gp120 has been isolated for animal experiments, it appears that this would not suffice for any larger scale human testing. This means that genetically-engineered gp120 or its pieces would be needed. A number of scientists and biotechnology firms have made products in the test tube, some of which have shown limited reactivity with the virus.

NIAID is also working on vaccine development. One of its staff scientists is developing a vaccine that will use the vaccinia virus (used for smallpox vaccination) to deliver the AIDS vaccine. This coming summer the Prevention Branch of the NIAID AIDS Program will convene a workshop on areas of research that should be emphasized. In addition, the NCI and NIAID solicited grant applications in late 1985 to do research on retrovirus vaccines including AIDS. Those applications have been reviewed for scientific merit, and awards will be made soon. Both Institutes also have awarded grants to scientists who have independently applied to conduct research on vaccines. All of this work, however, is at the preclinical stage. Although some preparations have been tested in animals, none are ready at this time for testing in humans.

Question 2: If an AIDS vaccine is discovered, it will have to be tested, first in animals and then in human beings. Is this correct?

Response: This is the normal process. A preparation would have to be shown to be safe in animals and to induce the right type of antibodies. In AIDS, no exact model comparable to man is available. The closest species, the chimpanzee, can be infected with HTLV-III, but so far, no clinical AIDS was ever observed. However, prevention of the initial infection with challenge HTLV-III in the vaccinated chimpanzee would suggest that the prevention of primary infection resulted from an effective vaccine. After safety and efficacy have been shown, human test populations can be considered.

Question 3: How do you propose to find human volunteers for such testing?

Response: NIAID has been assigned responsibility for the clinical testing of any AIDS vaccine that appears promising. The first tests to be done in humans are referred to as Phase I tests and seek to evaluate the vaccine's safety and antigenicity in small numbers of people. The Institute, because of its long term interest in vaccines, has already established contract supported Vaccine Evaluation Units, and these units have been very successful in attracting volunteers for the conduct of Phase I studies. The Institute intends to use these existing units for the testing of any vaccine that has shown promising results in the various pre-clinical testing regimens. Human volunteers that will be involved in any research conducted and or supported by HHS components, will be selected in accordance with the HHS Regulation for the Protection of Human Subjects, Title 45, CFR Part 46. The large scale testing required to establish the efficacy of a vaccine is the last study that is required before a product is licensed. Because of the scale of such testing, these populations may be difficult to identify and recruit. The Institute recognizes this fact, and another major objective of the planned AIDS Vaccine Workshop will be to address this issue so that appropriate plans can be made for the design of efficacy trials.

Question 4: An article in yesterday's New York Times addressed this problem. It pointed out that:

- o persons who already have AIDS will not benefit;
- o persons who do not have AIDS but have tested positive to antibodies would not be proper subjects for testing;
- o persons in high risk groups who have not been infected but who have adopted new life styles to avoid AIDS may not want to take the risk associated with experimental vaccines;
- o there would be ethical problems in encouraging vaccine recipients to resume dangerous life styles to determine whether the vaccine is effective.
- o How will you deal with these problems?

Response: It is true that, as with other vaccine preparations, the emphasis here is on prevention of further virus spread to virus-negative individuals. Because of the life cycle of HTLV-III which, as a retrovirus, becomes part of cellular DNA after infection, AIDS patients or antibody-positive persons already infected with the virus would not be suitable for vaccine testing. People who have so significantly changed their life style that they would not be exposed to virus would not necessarily have to be vaccinated. Currently, we do not foresee that large scale vaccination of not-at-risk individuals would be desirable. The question of ethical problems will always remain, but can be considered in a reasonable context. For example, the final efficacy of any vaccine will only be determined in man by prevention of infection and disease in a group of vaccinees who will be exposed to virus at some latter point. The encouragement of avoiding all high risk situations holds true for all individuals whether they have been vaccinated or not. Some exposure may be unavoidable, and it is with those cases that vaccine efficacy will be determined in man.

5. Question:

Are drug companies going to be reluctant to participate in vaccine production because of potential liability problems?

Response:

Drug companies have not expressed to FDA a reluctance to participate in AIDS vaccine production because of liability problems. However, it may be too early in vaccine development for them to assess the extent of potential liability concerns as such concerns will be dependent upon a vaccine's effectiveness, it's side effects, and the population to be immunized.

1. Question:

We read with interest last weekend that there is a new AIDS test being developed (by cetus) that detects the presence of the virus, not just the antibody. Presumably this will be a much more accurate test of infection with AIDS. Can you tell us a little about that test? Will this allow us to better protect the blood supply? When do you think it might be ready?

Response:

From published scientific papers and the press accounts, this technique as currently designed appears to be for the pro-virus, that is the DNA copy of the viruses genetic material which is found in infected cells. Using many cycles of probe directed enzymes which make new DNA copies, the number of pro-viral DNA copies is greatly expanded; these are then tested for using a pro-viral specific radiolabled DNA probe. Whether this test can be used for detecting virus as well as pro-virus, and whether it will work in biological products such as serum or blood, are questions that will have to be addressed in future research. Although this approach is promising, clinical trials will be needed to find out how sensitive and specific the technique might be.

Because of donor selection and HTLV-III antibody testing, the blood supply is already felt to be well protected. Whether this new test might add additional safety is hard to predict with our current knowledge.

Again, a considerable amount of laboratory bench work and field testing will likely be required before this test can be useful in screening or diagnosis.

QUESTIONS FOR CDC/NIH FROM SENATOR KENNEDY

1. Question: What progress has been made on updating and expanding the definition of AIDS?

Answer: Several outside consultants convened at the Centers for Disease Control (CDC) in April 1986 to participate in developing a classification system for manifestations of HTLV-III/LAV infection for public health use. This classification will include manifestations that have been called "AIDS" and "ARC," as well as asymptomatic infection. The proposed classification system is currently in draft form. The final version will be published in the Morbidity and Mortality Weekly Report (MMWR) within a few weeks. A similar meeting to develop a pediatric classification system is planned within the next few months.

Question 2: Is there any coordination with the Department of Defense?

Response: A number of NIH components have become involved with the Department of Defense (DOD) in coordination of efforts on AIDS. Staff, including the Director, of NIAID have met on several occasions with staff of the Assistant Secretary of Defense for Health Affairs and with staff from the Walter Reed Army Institute of Research, the DOD unit with primary responsibility for AIDS research. Areas of cooperation and collaboration have been discussed, including the possibility of DOD supporting an AIDS Treatment Evaluation Unit which may be integrated into the series of Units to be supported by NIAID and located around the country. An informal liasion has been established which will probably lead to more formal arrangements when DOD research plans are more fully developed.

The major interaction at NCI is with the Walter Reed Army Institute of Research. Close collaboration has existed for several years. There is a regular bilateral attendance at the laboratory level and joint publications have resulted. DOD has expressed an interest and consulted with NCI staff also in the distribution of their research funds on further collaborative projects.

The National Institute of Dental Research (NIDR) is initiating an interagency agreement with Walter Reed that adds an oral component to their major study of the natural history of HTLV-III/LAV infection and disease in a military population.

There are a number of areas of coordination related to AIDS between DOD and CDC. CDC staff participate periodically on the Armed Forces Epidemiology Board (AFEB) on issues related to AIDS. CDC staff also serve on the American Institute of Biological Sciences/U.S. Army Research and Development Command Retroviral Diseases Peer Review Panel, which assesses the scientific merit of AIDS and other extramural research grant applications. In addition, a CDC medical officer is detailed to the Armed Forces Institute of Pathology to assist with AIDS activities. DOD staff serve on the consultant group organized by CDC to establish a classification system for disease and infection associated with AIDS. There is direct, periodic communication about AIDS between the Preventive Medicine Consultants to the Army, Navy and Air Force and CDC. In addition, there are numerous direct informal technical consultations related to AIDS between medical and public health officers at DOD installations and medical treatment facilities and CDC personnel. AIDS cases occuring among military personnel are reported by the military treatment facility to CDC by the usual disease reporting channels through the local and State health departments. DOD also shares data related to the screening of military recruit applicants for infection with the AIDS virus directly with CDC. This information is an important adjunct to the national surveillance of AIDS, for which CDC is responsible.

Question 4: How many dollars were taken away from ongoing research projects last year and spent on AIDS research?

Response: It is not possible to estimate precisely the level of resources that have been redirected to AIDS research. Over the years, we have appropriately shifted resources to AIDS as we recognized its importance as a major infectious disease, and commensurate amounts have been built into our overall budget requests. In terms of additional funding provided by the Congress, however, we can state that a total of $87.2 million has been added to the NIH appropriations since FY 1982 specifically for AIDS research; our expenditures over that time are estimated to reach $267.6 million by the end of FY 1986.

CDC received approval to reprogram $1,250,000 from other research projects to fund start-up costs for AIDS alternate test sites.

Question 5: In your choice of priorities for intramural research, how many dollars were taken away from other projects for AIDS research?

Response: Additional funding provided by the Congress has not been applied to the intramural program to a significant degree. Again, we believe that the shifting of both dollars and individuals to the AIDS program has been appropriate. Researchers whose expertise was closely related to the scientific requirements of AIDS research were moved into that area as research opportunities were identified. It is hoped and expected that knowledge gained through AIDS activities will have a wide impact on progress in other related areas.

For CDC the approved reprogramming was for $5,400,000. Of this total, $1,250,000 was reprogrammed from research projects by funding the projects for less than 12 months in 1985. The projects were continued in 1986 for 12 months. This strategy did not affect or delay the research being performed under the contracts.

Another $1,500,000 was reprogrammed from STD grants, $2,400,000 was diverted from other AIDS projects using the short funding strategy to prevent affecting or delaying the AIDS projects, and $250,000 was diverted from planned purchases of scientific equipment.

Question 6: Of the $70 million which was allocated to the NIH last year in fiscal '85, how much has been distributed?

Response: A total of $70 million was provided in the FY 1986 appropriation of the Office of the Director, NIH, for allocation to the Institutes in response to emerging scientific opportunities. Of the $66,990,000 remaining after sequestration, $63,034,000 had been allocated as of May 2, 1986. It is anticipated that the remaining $3,956,000 will be allocated before the end of May.

Question 7: Have you been able to get that money as necessary?

Response: The NIH AIDS Executive Committee reviews all proposals submitted by the various Institutes and makes recommendations to the NIH Director. Generally speaking, this process takes less than one month.

Question 8: Have there been any delays?

Response: The uncertainties associated with the changes in the FY 1986 budget, the proposed rescissions, and the sequestration precluded early action on some proposals. Consequently, the first allocations were not made until January 1986.

Question 9: What is the total number of dollars of AIDS spending in your budgets sequestered? Rescinded?

Response :
- o The 1986 CDC budget after sequestering of $2,792,000 provides $62,133,000 for AIDS activities. The 1986 NIH budget after sequestering $6,051,000 provides $134,672,000 for AIDS activities.
- o After proposed 1986 AIDS activities rescissions of $11,848,000, the CDC budget request includes $50,285,000 for AIDS. After proposed 1986 AIDS activities recissions of $13,915,000, the NIH budget request includes $126,808,000 for AIDS.

Question 10: Can you tell us what effect that is having on AIDS research?

Response : AIDS research at NIH has been in an expanding growth mode since the beginning. There have been no negative effects at the bench or the clinical levels in getting the work accomplished.

Although some AIDS program activities are affected, AIDS epidemiologic and laboratory research at CDC is not adversely affected.

Question 11: What efforts have been reduced?

Response : All AIDS research efforts at NIH have been reduced 4.3 percent, the amount required by the sequestration.

The sequestering of AIDS funding affected the following CDC activities:

- Funds available to purchase chemotherapeutic agents for the treatment of patients with AIDS will be reduced by $297,000.
- The reduction of $86,000 for the 24-hour AIDS hotline will decrease the level of services available to the callers by reducing the number of telephone call receivers from 39 to 35.
- Alternate test site awards to States will be decreased by $446,000, or an average of $8,900 per State and will require additional State or local funding.
- The $1,963,000 reduction in other AIDS activities will reduce the average size of the award to States and local health agencies by 4.3% for health education/risk reduction activities in capacity building, augmentation of existing health education/risk reduction programs, and demonstration projects. Funds available to fund innovative health education/risk reduction projects will be reduced by 4.3%. The sequestering will also decrease the size and/or number of surveillance projects and epidemiology studies.

Question 12: What number of FTEs have been lost, if any, due to the sequestration and the rescission? As a reference point, how many have been lost over the last three years? Which AIDS-related projects have lost FTEs?

Response: Throughout the history of the AIDS research program at NIH, no FTEs have been lost in this area through any means, including sequestration, the proposed rescission, or reductions in overall FTE ceilings. The NIH AIDS program has grown from 27 FTEs in 1982 to an estimated 234 in 1986.

CDC did not lose any AIDS FTEs as a result of the sequestration or rescission.

Question 13: How much of the money appropriated to NIH last year went to investigator initiated research?

Response: We currently estimate that $18.4 million, or 14 percent, of the funds appropriated to NIH in FY 1986 for AIDS research will go to investigator-initiated research.

Testimony of Senator Alan Cranston
before the
Senate Labor and Human Resources Committee
Hearing on
Acquired Immune Deficiency Syndrome
April 16, 1986

Mr Chairman, I am pleased to have this opportunity to present testimony on the devastating AIDS epidemic. Since this crisis began, I have twice requested that hearings on AIDS issues be held by the Committee. Thus, I would like to express my appreciation to you for holding this hearing to examine what steps need to be taken this year and in the years to come to help bring us closer to stopping the spread of this deadly disease and, ultimately, to eliminate it -- and in the meantime, to provide for appropriate care of AIDS patients.

Scope of the Epidemic

Mr. Chairman, the United States is now in the sixth year of the AIDS epidemic. Nearly 20,000 people have developed AIDS. Approximately half have died. As of December 1985, close to 4,000 cases of AIDS were reported in my own state of California alone, and 4,000 more are projected for 1986. The California State Department of Health Services estimates that 12,000 individuals in California have AIDS-related complex (ARC) and about 300,000 persons more are infected with the AIDS virus. These numbers indicate clearly that the AIDS crisis is escalating and will be with us for years to come. The scope of the epidemic is far greater than many envisioned just a few years ago.

Although we must certainly address the immediate problems which AIDS presents, it is equally imperative that the Congress and the Administration also develop a comprehensive long-range plan for coping with the AIDS crisis. Even if a vaccine were discovered this year -- and that is highly unlikely -- tens of thousands, possibly hundreds of thousands, of the million Americans who are already infected with HTLV-III virus will develop AIDS. Thus, I urge the Committee to address the long-term projections regarding the incidence of the disease in order to anticipate and respond effectively to the growing crisis.

The battle plan against AIDS should include three integral components: research, education, and treatment. We must sustain our research efforts, respond to society's needs for information and education, and ensure that all AIDS patients are able to receive necessary and appropriate treatment and health care.

Research

During the first few years of the AIDS crisis, it was most critical to channel our efforts into basic research. Because of these efforts, scientists have made tremendous progress in deciphering the HTLV-III/LAV virus. Years of basic research have produced a solid scientific foundation for efforts to begin to develop effective therapies to treat AIDS and a vaccine making it possible ultimately to eradicate it. I want to express my admiration for and gratitude to the many scientists working on AIDS at the NIH and at research institutions around the country for their commitment and their superb efforts on AIDS.

Reports of new discoveries regarding AIDS are occurring with increasing frequency. They give us great hope that a vaccine is possible and may be developed in the forseeable future. I am also confident that drugs to check the virus and to stimulate the immune system will be found that will control and possibly cure AIDS.

Continued rapid progress on AIDS now requires both sustained basic as well as clinical research. We must maintain the momentum in our efforts to conquer this disease. Thus, I am pleased that the Congress has thus far declined to act on President Reagan's proposal to rescind $14 million in FY 1986 appropriations for AIDS research at the NIH. Unfortunately, however, the FY 1986 NIH budget for AIDS activities was reduced by $5 million as a result of the President's March 1, 1986, sequestration order under the Gramm-Rudman law.

Community Education and Risk Reduction

Last October we were successful in appropriating $20 million in FY 1986 for community health education and risk reduction for AIDS. Without a vaccine for a the HTLV-III virus, preventive action through such a program is our best hope for limiting the spread of infection. Reports from high-incidence communities with active education programs, like San Francisco and New York, indicate that education works. Epidemiological studies show that gay men at risk for AIDS are taking the necessary steps to reduce their infection risk.

Now is the time to implement education efforts in medium and low-incidence areas as well. In addition, health-care professionals need education and training concerning the most up-to-date information about AIDS patient treatment methodologies and information to help allay their concerns about working with AIDS patients. All Americans should have knowledge of the facts about AIDS and how it is transmitted. This knowledge can help stop both the epidemic of illness and the epidemic of fear.

Treatment and Health Care

Perhaps the greatest challenge in our fight against AIDS is how to ensure the availability of appropriate and necessary health care and treatment for all AIDS patients. The CDC recently released a study that estimated the cost of caring for the first 10,000 AIDS patients at more than $1.25 billion. The AIDS epidemic is placing increasingly greater burdens upon the health-care system. Cities and counties with a large number of cases are already feeling a strain from this burden.

The CDC estimates that the average hospital bill for an AIDS patient is $140,000. Some of those bills are privately financed through insurance or otherwise; many are not. The Health Care Financing Administration estimates that in FY 86, some $100 million in federal Medicaid funds will be expended for AIDS patients -- that is, for the approximately 40 percent of AIDS patients who have no other sources of payment.

I am very proud that San Francisco has developed a model network of out-patient services for AIDS patients -- including home-health care, support services, counseling, and hospice care -- that has resulted not only in lowered costs, but more compassionate and humane care. To assist other communities in setting up similar programs, Congress appropriated in the FY 1986 Labor-HHS-Education Appropriations Act $16 million for the establishment of 4 demonstration projects for the delivery of health-care services in community settings in high-incidence areas. In addition, the Robert Wood Johnson Foundation announced last February that it would award $17 million to up to 10 projects in 21 metropolitan areas with the largest AIDS case loads.

I urge your Committee to encourage this outpatient approach. It is cost-effective and enables communities to provide needed services to AIDS patients.

The FY 1987 Budget

President Reagan's FY 1987 budget proposal includes $213 million for AIDS activities -- public education and prevention, and research and development. This is $21 million less than the post-Gramm-Rudman level for FY 1986 and $31 million less than Congress originally appropriated for FY 1986.

The budget does not provide funds for continuing the demonstration projects on health-care and would drastically reduce the CDC's budget for public education and surveillance. Furthermore, it does not provide funding either to expand the clinical trials program to allow more AIDS patients to participate and more drugs to be tested, or to enhance vaccine development work. These projects are essential for bringing an end to this tragic epidemic as rapidly as possible. This is no time to lessen our commitment to or slow our support for finding the means to prevent, treat, and cure AIDS.

Conclusion

In conclusion, Mr Chairman, I urge the Committee on Labor and Human Resources to continue the efforts it has begun today on AIDS. Successfully conquering AIDS requires the best Americans have to offer: commitment, cooperation, and compassion. I am confident we can answer the challenge.

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Committee on Labor and Human Resources
United States Senate

RE: Acquired Immunodeficiency Syndrome

April 23, 1986

BACKGROUND

The AMA is very concerned about the public health threat posed by Acquired Immunodeficiency Syndrome (AIDS). As its name indicates, AIDS is a disease that attacks the body's immune system, leaving its victim subject to numerous opportunistic infections which ultimately lead to death. AIDS is transmitted through sexual contact, contaminated blood and blood products, and perinatally. Since 1981, the time of its identification as a distinct clinical entity, the number of cases of AIDS in the United States has steadily increased. As of April 1, 1986, over 18,500 cases of AIDS have been reported to the Centers for Disease Control; a doubling of this number is expected during the coming year. At this time no cure exists for AIDS.

In 1984, the infectious agent for AIDS was identified as the retrovirus HTLV-III. As many as 1,765,000 persons in the United States have been infected with the HTLV-III virus, and all are capable of transmitting it. A number of diseases in addition to AIDS have been attributed to HTLV-III infection, including thrombocytopenic purpura, central nervous system infections, "slim" disease and a variety of constitutional symptoms and infections collectively known as ARC (AIDS Related Complex).

On a worldwide level, AIDS has been reported on every continent with the exception of Antarctica. Because of its long incubation period (at least as long as 5 years, and possibly longer), the HTLV-III virus could have an adverse impact that may not be fully known until well into the twenty-first century. Unless current trends of infection with HTLV-III are slowed, AIDS has the potential of becoming the major lethal pandemic of the second half of the twentieth century.

To curtail the spread of AIDS and to control the disease in AIDS patients, three major scientific accomplishments are needed: (1) the development of an effective vaccine; (2) the development of anti-viral therapies; and (3) the development of methods for immune reconstitution. The AMA strongly supports government funding for stepped-up basic and clinical research concerning AIDS. In addition, if spending reductions must be made in federal health programs, agencies must be given the flexibility to allocate cuts so that essential AIDS research is not affected. Much more research is needed to develop appropriate methodologies and to document their clinical usefulness. Even with such research, however, the U.S. Public Health Service estimates that no scientific breakthrough is likely before 1990.

IMPORTANCE OF EDUCATION

Until a vaccine against AIDS becomes available, or until effective anti-virals are produced, the disease has the potential of spreading at an ever-expanding rate. The only effective means now available to stem the spread of AIDS is through behavior modification resulting from education about the disease and its modes of transmission. Education is also critically important to alleviate undue public concerns about AIDS.

As a major educational resource on health matters, physicians are important to the information-dissemination process. It is, therefore, essential that physicians practicing in communities throughout the nation and the world not only be as fully informed as possible about AIDS, but also that they share their information with patients and with the public in general.

AMA PLAN FOR AIDS

To ensure that physicians are well informed concerning all aspects of the AIDS problem, we have developed an "AMA Action Plan For AIDS." The primary purpose of this activity is to educate physicians concerning the scientific, medical, psychological, sociological and ethical aspects of AIDS and thereby equip them to be spokesmen about AIDS in their communities.

Health Education Project

The major focus of the AMA Action Plan at this time is a project for community health education and risk reduction. This project will be coordinated by the AMA and implemented through state medical societies. The four stages of the project include (1) development of an AIDS educational program; (2) presentation of the program to a core group of state medical society personnel who will later function as educators at the local and state levels; (3) training of community-based volunteer physicians interested in forming an AIDS speakers bureau; and (4) delivery of health education and information on AIDS to the general public.

In stage one, an educational program incorporating the most recent scientific, medical, ethical, and psychosocial information about AIDS will be developed by the AMA through physicians and other scientists who will have primary responsibility for formulating this educational program.

In the second stage, AMA will present the AIDS educational program in the form of one-day workshops. These workshops will be conducted at medical society facilities to an audience of physicians interested in becoming AIDS educators and to selected medical society staff. Conducting the workshops at state sites offers the opportunity to provide information to a large number of prospective AIDS educators in a flexible training program. Further, it allows physicians an opportunity to express and discuss AIDS-related problems and concerns particular to that area. The core group of physician-educators will be selected by state medical societies from among those who currently serve on local AIDS committees or express interest in becoming AIDS educators. One staff person from each state medical society will be designated to serve as the local task force coordinator and AMA liaison. This individual will be responsible for identifying and organizing physician educators and will receive updated information concerning AIDS from the AMA as it becomes available.

In stage three, AIDS physician-educators will train community-based volunteer physicians interested in comprising an AIDS speakers' bureau. A call for volunteers will be publicized through state and city medical society communication networks. Physicians from all specialties interested in becoming part of an AIDS speakers' bureau will be solicited and given state-of-the-art AIDS information, basic public speaking training, and printed educational materials. The training given to community volunteer physicians will be a condensed version of the full AMA AIDS educational program.

Stage four entails the delivery of health education and information on AIDS to the general public. The designated AIDS coordinator in each state will work with local American Red Cross chapters and the state health department to match individual physicians from the speakers' bureau to audiences. Various community groups, high schools, and industrial settings may be typical outlets.

In order to provide services in a timely fashion and ensure programmatic quality, we are launching our health education project on a pilot basis in four states this spring: California, Illinois, Pennsylvania and Texas. The following criteria were utilized in selecting pilot project states:

- State medical society interest and current organizational capability to work on an AIDS health education project in cooperation with the AMA;
- A perceived need on the part of the state medical society for community health education on AIDS;
- Adequate existing support from American Red Cross networks;
- Geographic representation of the nation's major regions;
- At least a moderate incidence-rate of AIDS.

Other Information Sources For Physicians

The AMA will continue to provide accurate and current information to physicians concerning AIDS prevention and treatment through the Journal of the American Medical Association (including publication of the Centers for Disease Control's Morbidity and Mortality Weekly Report), American Medical News, and the reports of the AMA Council on Scientific Affairs. In addition, the AMA will continue to serve as an information clearinghouse and referral center for physician questions concerning AIDS. We are also in the process of publishing a special book on AIDS entitled "AIDS From the Beginning". Finally, we will be holding a national conference on AIDS in October. The conference, which will be oriented to business and community leaders, will focus on the medical and sociological aspects of AIDS.

Education of the Public

The AMA will embark on a major effort to inform the public concerning AIDS. The primary means of public education will be through our health education project. In addition, we intend to provide information directly to the public through a number of sources including AIDS pamphlets for physicians' offices and stories about AIDS on "American Medical Radio News."

Conclusion

AIDS is an extremely serious public health problem. Until effective medical therapies are developed, the only means of stopping the spread of AIDS is through behavior modification resulting from education about AIDS and its modes of transmission. Education is also important in order to allay unwarranted public fears about AIDS.

The AMA has undertaken a major effort to disseminate information about AIDS to physicians and to encourage them to be proactive in sharing their information with patients and the public. We are hopeful that our effort along with those of other groups will help in curbing the spread of this terrible disease.

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STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION TO THE SENATE LABOR AND HUMAN RESOURCES COMMITTEE ON ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

May 5, 1986

The American Hospital Association (AHA), which represents 5,600 health care institutions and 40,000 personal members, appreciates the opportunity to present its views on the AIDS epidemic--its impact on hospitals and the activities of the AHA to educate its membership about the AIDS virus and the treatment of AIDS patients.

Acquired Immunodeficiency Syndrome (AIDS) has been labeled the nation's top health priority. As of January 1986, 16,000 cases of AIDS had been reported nationwide. With that number expected to double every 10 to 12 months, AIDS can no longer be considered a problem confined to hospitals in New York City and San Francisco. Every state now has an AIDS population and the AHA has worked diligently to provide its member hospitals with up-to-date AIDS-related information through educational seminars, written guidelines, video-teleconferences, and staff consultation.

But the impact AIDS has on the hospitals goes far beyond staff education. Some hospitals treating large numbers of AIDS patients have set up specialized medical, nursing, psychiatric, social and support services to meet patients' need. Many hospitals are working to reduce the cost of care, by reducing length of stay in the acute-care setting and devoting increased resources to outpatient treatment, home, and hospice care. The cost of providing care to patients with AIDS has been shown by one study to be approximately $140,000. Other estimates have been lower than this figure, but all data indicate that this is very expensive disease to treat -- patients require more intensive medical, nursing and social services than the average patient. Many, in the latter stages of their illness, become reliant on Medicaid, which usually does not cover the hospital's full costs. Thus far, urban, public hospitals have borne a disproportionate share of the responsibility for the care of these patients.

Compounding the cost problem is one of discrimination in the availability of post-hospital care. On any day in any large city, many patients with AIDS have reached the point in their treatment when they no longer require the acute care a hospital provides. Yet they are unable to care for themselves at home. Where do these patients go? All too often the answer is "nowhere." Most nursing homes still do not admit these patients--some because they are afraid; most because they are unwilling to assume the financial liability, either real or perceived, these patients present. Hospitals, nursing homes, and the government must work cooperatively to alleviate this problem.

If current trends continue, hospitals' financial pressures due to treatment of AIDS patients can only increase. The incidence of AIDS among intravenous drug abusers is increasing. One study in New Jersey indicated at least one-third of the drug abusing population carries the AIDS virus antibody. This population is costlier and more difficult to treat, poses significantly greater post-hospital placement problems, and is much less likely to be covered by health insurance. Federal budgetary constraints also are creating pressures to limit Medicaid expenditures, which could result in limitations on hospital Medicaid payments.

In 1983, anticipating our membership's need for assistance in dealing with AIDS, a special advisory committee was convened to draft a set of guidelines for the nation's hospitals. These guidelines, which stressed education of employees, patients, and the public, were sent to member hospitals and another 600 copies were distributed in response to requests from the public. Many of these requests were from institutions other than hospitals and a few were from foreign embassies. In January of 1984, a live, interactive, video-teleconference was broadcast to an audience of approximately 3,000 viewers across the country.

Throughout the next 18 months, the AHA experienced an increasing volume of requests for additional information regarding AIDS from its membership and allied health associations. The Association responded by pledging time and resources to the education of its institutional and individual members with the goal of the uninterrupted provision of high quality health care to the patients with this disease. Among AHA's activities:

- The original guideline document was revised and updated. This was mailed to all member hospitals and to individuals and organizations requesting a copy. These guidelines have been adapted for use in other industry settings. A copy has been enclosed for the record.

- A second three-hour, live, interactive video-teleconference was broadcast to more than 400 sites in January 1986. Hospitals were encouraged to open their doors to pre-hospital and post-hospital care givers, to other professionals in the community who may give service to AIDS patients, and to community policy makers. The resulting audience of over 14,000 viewers included school nurses, emergency medical personnel, morticians, hospice volunteers, and fire department personnel in addition to hospital personnel.

- A 20-minute videotape for inservice education of hospital personnel was produced and is available to members for only the price of shipping and handling. This tape explains to the viewer both the precautions necessary (and those that aren't) when caring for patients with AIDS, and some of the emotional needs of these patients that staff should be aware of and responsive to. More than 400 copies have been mailed in the three months it has been available.

- AHA presented a series of educational programs addressing the legal and employee issues related to treatment of AIDS patients.

- An ad hoc committee of AHA staff has been established to coordinate meeting the educational needs of the membership and to ensure that the information coming from AHA is timely and consistent with the goals of providing uninterrupted, quality health care.

- A new, multi-disciplinary Advisory Committee of experts has been established to guide the AIDS activities of the AHA through identification, analysis, and assessment of emerging AIDS issues. This committee has representation from the fields of healthcare management, law, ethics, insurance, health economic policy, and epidemiology.

- AHA is conducting educational programs to teach hospital staff how to cope with the severe psychological impact of caring for AIDS patients. Emphasis is also being given to training staff to sensitively address the unique psychological needs of patients, family, and friends.

- The AHA is acting as a resource and a clearinghouse for the activities of state and metropolitan hospital associations.

- AHA currently is developing a packet of information on ways hospitals can educate the community and encourage responsible reporting by the press.

Feedback from the users of both the written and video materials indicates that there has been a very positive impact on the behavior of the staff who treat patients with AIDS as a direct result of these materials.

The health care community has learned an enormous amount about AIDS; it also has learned that there is still much more that we need to know. Though the federal budget deficit should be trimmed, it is important that resources be maintained for AIDS education, treatment, and research.

PUBLIC HEALTH SERVICE PLAN FOR THE PREVENTION AND CONTROL OF AIDS AND THE AIDS VIRUS

Report of the Coolfont Planning Conference
June 4 to 6, 1986

Foreword

In 1985, the Public Health Service's Executive Task Force on AIDS published a comprehensive plan that included a set of objectives to control and prevent the spread of acquired immune deficiency syndrome by the year 2000. In the year since the plan was developed, considerable progress has been made. Our knowledge base has expanded many fold, and our cumulative 5 years of experience with AIDS and HTLV-III/LAV (HIV)* infection has provided new information that permits tentative long-range demographic projections, a better understanding of pathogenesis, a refined approach to research and development of vaccines and therapeutic agents, a refocus of prevention and control efforts, and the incorporation of patient care issues.

The Public Health Service (PHS) convened a meeting at the Coolfont Conference Center in Berkeley Springs, WV., June 4-6, 1986. Eighty-five experts in various aspects of AIDS, including clinicians, epidemiologists, public health policy makers, and basic research scientists were invited to review and modify the plan according to current information, needs, and demographic projections through 1991. The following plan is the result of that meeting; it represents a renewed commitment by the Public Health Service to prevent and control HTLV-III/LAV infection and its sequelae.

Purpose

This document provides a framework for the steps that must be taken in five broad areas--pathogenesis and clinical manifestations; therapeutics; vaccines; public health control measures; and patient care and health care needs--to achieve prevention and control of AIDS. The current plan is based on estimated changes in the demographics of AIDS through 1991. It calls for concerted action by Federal agencies, State and local health departments, professional organizations, and volunteer groups.

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*HTLV-III/LAV = Human T Cell Lymphotropic Virus Type III/ Lymphadenopathy Associated Virus. The name human immunodeficiency virus (HIV) has been proposed for these viruses by the International Committee on the Taxonomy of Viruses.

Goals

The following goals were first published in the 1985 plan and remain valid for guiding the continuing National effort.

- By 1987, reduce the transmission of the HTLV-III/LAV infection.
- By 1990, reduce increase in the incidence of AIDS.
- By 2000, eliminate transmission of HTLV-III/LAV infection with a decline in the incidence of AIDS thereafter.

Background

Five years have elapsed since the initial report of *Pneumocystis carinii* pneumonia from Los Angeles marked the recognition of what has become known as AIDS. By 1984, a human retrovirus, HTLV-III/LAV, had been determined to be the etiologic agent of AIDS and, by early 1985, serologic tests for antibody to the virus were licensed and widely available.

In retrospect, when AIDS was initially reported in June 1981, some 5 years already had elapsed since the introduction of HTLV-III/LAV into the United States, and 3 years had elapsed since the first clinical cases had occurred. AIDS cases have been reported from all 50 States, the District of Columbia, and four Territories. Cases have been reported from more than 100 foreign countries.

The rapid development and implementation of sensitive and specific assays for HTLV-III/LAV antibodies have permitted screening of donated blood and plasma, and the research use of these and other assays has elucidated the modes of transmission, the natural history of infection, and a better understanding of the clinical manifestations of HTLV-III/LAV infection .

The predominant defect in AIDS is a profound and, so far, irreversible immune dysfunction that results when HTLV-III/LAV preferentially infects the helper- inducer subset of T-lymphocytes. Although the virus can also infect other cells of the immune system, as well as cells of the central nervous system, it is the infection of these T-lymphocotes that ultimately leads to a breakdown in the ability of an infected individual to mount an immune response. In the past 5 years, more effective therapies for some of the opportunistic infections that accompany AIDS have been found, but no cure for AIDS is yet available.

Studies of the molecular biology of HTLV-III/LAV have revealed that a copy of the viral genetic material becomes an integral and permanent component of the DNA of an infected individual. As a result, such an individual is likely a carrier of the virus for the rest of his life and, for purposes of public health control, is assumed to be capable of transmitting the virus to others.

The HTLV-III/LAV genome has been completely sequenced and the function of several of its genes are known. Considerable differences in some genes have been found among various isolates. In addition, related viruses have been identified in man and nonhuman primates. These related viruses cause a range of different diseases. Studies in animals indicate the feasibility of vaccination against retroviruses, and one veterinary vaccine is available for the prevention of feline leukemia virus. Although some promising approaches are under way, as yet no effective vaccine for AIDS exists.

HTLV-III/LAV is transmitted by sexual, parenteral, and perinatal contact with the virus. Although this infection has been most often recognized in homosexual men and intravenous (IV) drug abusers, it is clear that this virus does not discriminate by sex, age, race, ethnic group, or sexual orientation. Behaviors which are high risk for the acquisition of HTLV-III/LAV infection include sexual contact or sharing of drug injection equipment with an infected person. Studies now clearly demonstrate that AIDS is not spread by casual contact, such as sneezing, coughing or sharing meals with an AIDS patient.

There are 21,517 cases of AIDS reported in the United States as of June 1986. Blacks and Hispanics represent 39 percent of total cases. Women who report no history of IV drug abuse represent half of the 1400 cases in women. Approximately 304 cases of AIDS occurred in infants and children under age 13. Between 2 and 3 percent of the cases have occurred in transfusion recipients or hemophiliacs. With the routine use of the HTLV-III antibody test to screen donated blood and plasma, use of chemical and heat treated, clotting factors, and donor deferral practices, we can expect to see this percentage reduced in future years..

Projected Cases of AIDS*
United States

CATAGORY	1986	1991	1991 Range
Cases Diagnosed			
Cumulative cases at start of year	19,000	196,000	155,000 to 220,000
Diagnosed during year	16,000	74,000	46,000 to 91,000
Alive at start of year	10,000	71,000	50,000 to 83,000
Alive during year	26,000	145,000	96,000 to 180,000
Deaths			
Cumulative deaths at start of year	9,000	125,000	103,000 to 137,000
Deaths during year	9,000	54,000	37,000 to 64,000
Cumulative deaths at end of year	18,000	179,000	142,000 to 201,000
Infections			
Persons with HTLV-III/LAV infection	1,000,000 to 1,500,000 (estimate)		

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*These numbers refer only to those cases that meet the CDC definition for AIDS (see Morbidity and Mortality Weekly Report, 1985: 34: 373-5) and do not include other manifestations of infection, such as AIDS-related complex and lymphadenopathy syndrome.

Projections

The following projections, as well as those in the table, are based on the Centers for Disease Control (CDC) surveillance data and epidemiologic studies of populations at high risk to infection with the virus.

- Twenty to 30 percent of the estimated 1 to 1.5 million Americans infected with HTLV-III/LAV as of June 1986 are projected to develop AIDS by the end of 1991. The latency period between infection and overt AIDS averages 4 or more years in adults, therefore, most persons who will develop AIDS between 1986 and 1991 will be those who are already infected with HTLV-III/LAV.

- Based on an empirical model that uses reported cases of AIDS, by the end of 1991, the cumulative cases of AIDS in the U.S meeting the CDC surveillance definition will total more than 270,000. During 1991 alone, more than 145,000 cases of AIDS will require medical care and over 54,000 AIDS patients are predicted to die, bringing the cumulative number of deaths due to AIDS to over 179,000.

- The empirical model may underestimate by at least 20 percent the serious morbidity and mortality attributable to AIDS, because of underreporting or underascertainment of cases.

- In 1985, 9,000 cases of AIDS were diagnosed in the United States and reported to the Centers for Disease Control. The empirical model predicts that cases will continue to increase through 1991, that there will be nearly 16,000 cases reported in 1986, and more than 74,000 cases projected for 1991. The estimates for 1991 range from 46,000 to 90,000.

- More than 70 percent of the cases will be diagnosed among homosexual or bisexual men, and 25 percent of the cases will occur among IV drug abusers with some overlap to continue between the groups. Because the periods between infection and disease are long and variable, cases will continue to be reported among transfusion recipients and persons with hemophilia.

- Additional cases in heterosexual men and women are projected, the 1,100 (7 percent of the total) for 1986 will increase to nearly 7,000 (more than 9 percent) by 1991. This group includes patients who reported heterosexual contact with an infected person or someone in a risk group, as well as cases in groups in which epidemiologic studies suggest heterosexual transmission as the major risk factor. By 1991, more than 3,000 cases will have been diagnosed in infants and children.

- Through 1985, fewer than 60 percent of cases were diagnosed in persons outside New York City and San Francisco, but by 1991 more than 80 percent of cases are predicted to be reported from other States and localities.

- Homosexual-bisexual men and men and women who use drugs of abuse intravenously will continue to be the populations at highest risk for HTLV-III/LAV infection during the next 5 years. Using estimates published by Kinsey, over 2.5 million (4 percent) of U.S. men between 16 and 55 years of age are exclusively homosexual throughout their life; an estimated 5-10 million more will have some homosexual contact. An estimated 750,000 Americans inject heroin or other drugs intravenously at least once a week; a similar number inject drugs less often.

- The prevalence of HTLV-III/LAV seropositivity among homosexual men and IV drug users parallels the frequency of AIDS in various cities. In 1984-85, 20 to 50 percent of homosexual men participated in research studies had evidence of HTLV-III/LAV infection. Similarly, seroprevalence estimates among IV drug abusers ranged from 10 to more than 50 percent in various U.S. cities. By extra- polating all available data, we estimate that there are approximately 1 to 1.5 million infected persons in those groups at the present. Thus estimates of a 20 to 30 percent progression to AIDS by 1991 in this group are consistent with the total number of AIDS cases predicted by the empirical model.

- Uninfected homosexual men have continued to acquire HTLV-III/LAV infections during the past year, but at a lower rate than would be predicted from the increases in previous years and from the increase in the number of potentially infectious persons. This observation is consistent with changes reported in sexual behavior and declines in other sexually transmitted infections in homosexual men. Nonetheless, due to the large present and future populations at risk, hundreds of thousands of additional homosexual men, IV drug abusers, and others may become infected during the next 5 years.

- Because of heat and chemical treatment of clotting factor concentrates, donor deferral, and serologic screening of donated blood and plasma, only a very small number of additional infections are likely to occur through blood and plasma transfusions.

- o Current information in insufficient to predict the future incidence of HTLV-III/LAV infection in heterosexual populations, but increases in heterosexual transmission are likely. Those at highest risk will be heterosexual sexual partners of infected persons and those who have sexual contact with past or present IV drug abusers, bisexual men, prostitutes, or others at increased risk for HTLV-III/LAV infection. As is true for homosexual men, sexual contact with multiple partners will increase one's risk for HTLV-III/LAV infection.

- o Additional increases in HTLV-III/LAV infection in infants are expected as more women in child-bearing years become infected.

The following five sections are the deliberations and recommendations made by the work groups at the Coolfont meeting.

I. PATHOGENESIS AND CLINICAL MANIFESTATIONS

Infection with HTLV-III/LAV results in a broad range of clinical manifestations including an acute retroviral syndrome, asymptomatic disease, chronic lymphadenopathy, and serious diseases including Kaposi's sarcoma and other malignant neoplasms, fatal opportunistic infections, and neurological and psychiatric disorders.

The factors that determine the expression and progression of disease in an individual are largely unknown. Techniques are available to diagnose and treat many of these opportunistic diseases, although they often recur. However, once Kaposi's sarcoma or certain opportunistic infections occur, an ultimately fatal outcome for the patient has been the rule..

Conclusions

Clinical and epidemiologic studies need to be conducted to:

- o Clarify the natural history of infection including the role which may be played by exogenous or endogenous factors in determining which clinical manifestations occur; and

- o Continue to expand the spectrum of clinical manifestations.

Basic scientific studies need to be expanded on the virology and immunopathogenesis of HTLV-III/LAV, especially to:

- o Assess target cell susceptibility;

- Identify viral and host cell determinants of transmissibility and pathogenicity including portals of viral entry, mechanisms of cytopathic effects, and dysfunction;
- Further elucidate mechanisms of viral latency and activation;
- Identify and assess direct and indirect immunopathogenic mechanisms;
- Further delineate the pathogenesis of neurologic and psychiatric abnormalities; and
- Ascertain more fully the functions of viral gene products and determine the meaning and mechanisms of genetic heterogeneity.

More suitable animal models for HTLV-III/LAV infection need to be developed to allow more comprehensive understanding of pathogenesis and rapid evaluation of treatment and prophylaxis. Dedicated efforts must be made to maximize efficiency of use of limited animal resources.

Improved methodologies are needed to detect infected and infectious individuals and to identify and quantitate virus, viral antigen, and viral antibody.

II. THERAPEUTICS

No drug with proven clinical efficacy for AIDS is currently known. Both antiviral agents and immunomodulators are being developed, and several drugs are under clinical investigation at present. The ability of an agent to reverse the disease process or halt its progression may vary depending upon the stage of infection. Research is now in progress to develop new methods to inhibit viral replication and correct the immune deficiencies. A safe and effective antiviral agent is nt likely to be in general use for the next several years. Experimental products are also under study for treatment of opportunistic infections and neoplasms associated with HTLV-III/LAV infection.

Conclusions

- Further expansion of the multi-institutional, multidisciplinary approach to identify and develop agents for the treatment and prevention of HTLV-III/LAV infection and associated diseases, including central nervous system disease, is necessary. Part of this effort must be the establishment of a large capacity screening program to measure the antiviral, immunomodulators and toxic effects of newly identified natural and synthetic compounds.

- A system for classifying HTLV-III/LAV associated disease manifestations which is useful in the design, implementation and analyses of therapeutic trials must be developed. Standard clinical criteria for the measurement of efficacy and toxicity must be formulated to facilitate the performance of well organized multicenter clinical trials.
- The most efficient design of clinical trials of candidate antiviral agents will require the use of placebo controls.
- New therapeutic approaches must be developed to control or eliminate latent virus and to specifically direct antiviral compounds to the appropriate target tissues. Combination strategies to control viral replication and restore the immune system must be developed and evaluated.
- Since antiviral drugs currently under development are likely to repress rather than eliminate the AIDS virus infection, long-term therapy is expected and with it the emergence of drug-resistant strains.
- New and/or existing strategies in the diagnosis, treatment, and prophylaxis of the opportunistic infections and neoplasms associated with AIDS all need to be developed, tested, and improved.

III. VACCINES

A number of vaccine candidates for human beings are currently under development and limited clinical testing for some could begin within 2 years. Field trials to demonstrate efficacy may require additional years. Vaccines are not anticipated to be useful in individuals who are already infected. A vaccine for general use is not anticipated before the next decade and its use would not affect the number of persons infected by that time.

Conclusions

- Vaccines employing recombinant DNA derived antigen, subunit, killed viruses, synthetic peptide, live recombinant, live-attenuated, and antiidiotypes will need to be evaluated as potential candidates for human trials.
- Vaccination methods will need to be devised to induce immunity to antigenically distinct strains of HTLV-III/LAV.
- Reliable in vitro and in vivo systems need to be developed for the evaluation of vaccine immunogenicity safety and efficacy before commencing trials in humans.
- A program for clinical and field evaluation of vaccine(s) needs to be established, including resolution of difficult aspects of design such as identification of target populations and the definition of parameters of vaccine efficacy.
- Protocols need to be developed for the in vitro and in vivo evaluation of anti-HTLV-III/LAV immunoglobulin to explore its value in passive immunization.

IV. PUBLIC HEALTH CONTROL MEASURES

In the absence of a vaccine and therapy, prevention and control of HTLV-III/LAV infection depends largely upon effective approaches to decrease sexual transmission, transmission among IV drug users, and perinatal transmission from infected mothers. A strategy to control and prevent AIDS should involve voluntary counseling and testing* for persons at increased risk of HTLV-III/LAV infection and imparting to infected patients those Public Health Service recommendations concerning personal behaviors that must be observed if spread of the virus is to be halted.

Public health activities directed toward the control and prevention of AIDS have required significant funding and staffing at national, State, and local levels. The projected increases in AIDS and HTLV-III/LAV infection over the next 5 years will pose substantial continuing demands for resources for these efforts.

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*Throughout this section, serological testing is intended to be voluntary, conducted with confidentiality, and accompanied by appropriate pretest and post-test counseling.

Conclusions

The recommendations of the conference participants concerning public health measures focused on five areas.

1. Information Base

   - o Information is needed to better determine the size of the population at greatest risk in the United States, particularly the numbers of homosexual men, bisexual men, IV drug abusers, and heterosexuals who have multiple partners.

   - o Better information is needed on the number of persons infected with HTLV-III/LAV. Extensive and repeated seroepidemiologic surveys are needed to determine the incidence and prevalence of infection by age, race, ethnicity, sex, geographic area and sexual preference. States should be encouraged to obtain and report data on incidence and prevalence to CDC for publication.

   - o The Public Health Service should encourage and assist in the evaluation and comparison of all interventions for prevention and control of AIDS and HTLV-III/LAV infection.

   - o PHS should continue to support key epidemiologic studies, such as modes of transmission.

   - o The United States should continue to play a role in understanding and assisting efforts to control the disease worldwide, particularly in areas with seemingly different epidemiologic patterns.

2. Information and Education

   National information and education campaigns on AIDS and HTLV-III/LAV infection should be targeted to individuals and groups whose behavior places them at high risk for AIDS, other sexually active adults, adolescents, preadolescents, and health care providers. A major target of mass information-education programs is the currently uninfected population, to assure that those persons know how to protect themselves. An additional purpose is to persuade infected persons to take appropriate steps to safeguard their own health and to avoid infecting others.

- PHS should explore the advantages of using paid radio, TV and printed media advertising as well as public service announcements to inform the public on AIDS and HTLV-III/LAV infection.

- PHS, State and local health departments, State and local boards of education, colleges, universities, and other organizations should support and encourage comprehensive education about AIDS and HTLV-III/LAV infection.

- With the assistance of appropriate organizations, programs should be implemented to provide culturally sensitive, meaningful information and education to blacks, and Hispanics including homosexuals, IV drug abusers, blood donors, women both at risk themselves and also at risk for transmitting infection perinatally and other other segments of the public

- Health care providers need current information and training on the diagnosis, psychosocial counseling and management of HTLV-III/LAV infected persons.

3. Prevention of IV Drug Abuse Transmission

IV drug abusers serve as the major reservoir for transmission of infection to heterosexual adults and their infants, as well as among themselves. As a group, they are not well organized, often poorly educated, and tend to have less interaction with the health care delivery system than other groups who participate in high risk behaviors. Efforts to change drug abuse behavior must proceed with the understanding that addictive behavior is not often changed without specific drug treatment.

- A systematically increased capacity for treating IV drug abusers is needed. Until adequate capacity is available, persons in need of treatment should be prioritized. Decisions may vary by locality, but highest priority should be given to those presently on waiting lists for treatment.

- All treatment and prevention approaches should include information and counseling on sexual and perinatal transmission of HTLV-III/LAV, availability of family planning services, and availability of voluntary serological testing for HTLV-III/LAV.

- o Until treatment capacity is adequate for persons who continue to abuse IV drugs, studies are needed to evaluate the efficacy and feasibility of promoting safer use of drug paraphernalia (for example, increased availability of sterile needles or "works") and education regarding use of sterile needles and sharing of needles.

4. Prevention of Sexual Transmission

Sexual contact will remain the primary mode of HTLV-III/LAV infection for the foreseeable future, with greater increase in the proportion of heterosexual transmission over the next 5 years.

A central goal of local disease control programs should be to reach the greatest number of HTLV-III/LAV infected persons with testing and counseling (provision of pretest and post-test information, including psychological support) about their infections and methods to reduce the likelihood of transmission to others, in order to change high risk sexual behaviors). At present, only a small proportion of the already infected population has been reached.

Several methods may help achieve this goal, although they may have differing efficacies in various settings and populations. These include encouragement of voluntary serological screening, self referral of sexual and/or drug abuse contacts, notification and counseling of contacts by health authorities, and targeted educational programs.

- o Serological testing of persons whose behavior places them at risk should be encouraged and made widely available. In all communities, appropriate medical care encompasses offering counseling and testing to all persons at risk, including persons with a sexually transmitted disease, IV drug abusers, and persons seen in private practice who engage in high risk behaviors. (Anonymous testing should be available as an option.)

- o Self-referral of an infected person's sexual and needle-sharing contacts should be encouraged. In some areas or populations, additional contact notification activities may be offered to infected persons by the health agency.

- o Research is needed on the efficacy of counseling and/or knowledge of personal serological status or both in modifiying sexual and needle sharing behavior to reduce or eliminate the risk of transmission.

- For persons who know that they are infected with HTLV-III/LAV yet continue to practice high risk sexual or needle-sharing activities, temporary involuntary isolation should be considered an option only in rare instances and after due process. Enforced isolation is not a practical way to minimize spread of the infection, since infected persons remain infectious for life. Education, counseling, and extension of social services--including drug treatment--are the main interventions for dealing with this problem and are appropriately applied to recalcitrant infected persons and their potential consenting partners. Uninfected persons must avoid behavior which would permit infection from persons who know or do not know they are infected.

5. Prevention of Transmissibility by Blood and Blood Products

The risk of transmission of HTLV-III/LAV by transfusion of blood and blood products is extremely low due to deferral of high risk donors, serological screening of donated blood and plasma, and the heat and chemical treatment of clotting factor concentrates. Nonetheless, some additional measures are appropriate to further reduce this low risk.

- Increase the effectiveness of deferral by all persons at increased risk of HTLV-III/LAV infection by:
    - Collecting demographic and other data from donors found to have confirmed HTLV-III antibody. This will require some type of case reporting and subsequent interviews, but it is essential to the continued evolution of the high risk donor deferral strategy;
    - Improving communications to potential donors about self-deferral, taking into consideration their language skills and literacy;
    - Exploring the usefulness of providing means at the time of donation for blood donors, who do not self exclude but who have remaining doubts about their suitability, to designate that their donated unit not be used for transfusion.
    - Implementing the use of a signed donor consent form in all blood banks that clearly indicates the absence of specific risk factors for transmission of infections.

- Continuing to require that blood and plasma establishments maintain deferral lists of donors who have repeatedly reactive ELISA tests.
- Continuing to encourage development and use of more sensitive serologic tests for HTLV-III/LAV infection.
- Recommending that current recommendations for HTLV-III antibody testing for donors of organs, tissues, cells and semen be made mandatory.
- Encouraging increased activities to eliminate unnecessary transfusions.

V. PATIENT CARE AND HEALTH CARE NEEDS

Over the period of 1986 to 1991, AIDS and associated conditions will place an increasing burden on the health care delivery system through an increased number of patients and increased costs of care. The burden will be shared by a larger number of communities, including some which will have a less complete capacity for response. There will be increasing fragmentation and less health care control of services provided if more non-medical, less traditional and some unethical providers become involved.

PHS estimates that the direct health care costs of persons with AIDS will be between $8 to $16 billion* in 1991. These sums represents 1.2 to 2.4 percent of the expected total U.S. personal health care expenditures in 1991 of about $650 billion. Because people with AIDS are concentrated in certain urban centers, however, these costs will be disproportionately borne.

These estimates may be conservative by 10 to 50 percent because of the increase need for care for the large population of patients with the other conditions associated with HTLV-III/LAV infection and the significant non-medical care costs necessary for management of these illnesses. Development of community-based health and social services support systems can reduce costs and enhance care during this five year period.

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*The $8 billion figure is based the projection of 71,000 AIDS patients alive in 1991 and 74,000 new cases by then. An additional 29,000 cases was added to account for the 20 percent underreporting or underascertainment of cases. The cost for treating a patient with AIDS used in the calculation was $46,000. For the higher range, the $8 billion figure was doubled.

Conclusions:

- Develop a coordinated Federal, State, and local response to manage the health services and health financing crisis posed by the escalating AIDS epidemic. This response must reflect the pluralistic character of the American health care system, and must involve the coordinated participation of the public, private and voluntary sectors, as well as ambulatory, in-hospital and long term care providers;

- Explore the feasibility and need for convening a national, blue-ribbon Commission representing the necessary constituencies to canvass needs and resources available and to make recommendations regarding how each sector of our society can help to fill financing and resource needs;

- Emphasize the needs of institutional and community-based providers for training, continuing education, and psychosocial support;

- Upon request, assist State, local governments, and community-based organizations to assess, develop and implement comprehensive service delivery systems of care for AIDS patients in a cost-effective manner;

- Develop organized consortia of service delivery systems responsive to the care of AIDS patients; such consortia should include all the necessary components of care (that is ambulatory hospital, mental health, and dental health services, counseling, home health care, and hospice care.)

- Explore efforts to set up regionalized consortia of services for AIDS patients;

- Utilize studies of the special health services needs and barriers to prevention of HLTV-III/LAV infection in blacks and Hispanics, and best methods of information dissemination to foster inclusion of culturally sensitive service delivery for children with AIDS, IV drugs abusers, hemophiliacs, and minorities in all appropriate metropolitian areas;

- Initiate demonstrations of the appropriate care needed at different stages of the illness, costs of services, and more cost effective provisions of needed services, inculding Model Medical Waiver progarms;

- Support health services research on AIDS that emphasizes cost of services for different risk groups, stages of illness, and treatment modalities and assesses potential improvement of methods and increased cost-effectiveness of care.

February 1986

The Nonprofit Sector's Response to the AIDS Epidemic: Community-Based Services in San Francisco

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ABSTRACT

Community-based organizations in San Francisco have played a key role in providing social support services and public health information to those affected by AIDS. These services have helped minimize the economic impact of the epidemic by reducing the level and expense of hospitalization of AIDS patients.

During Fiscal Year 1984-85, the three largest community-based groups provided more than 80,000 hours of social support and counseling services, responded to over 30,000 telephone inquiries and letters and distributed nearly 250,000 pieces of literature. Home-based hospice care was provided to 165 AIDS patients at an average cost per day of $94.

Community-based organizations require a significant level of funding from government and private sources. Local government in San Francisco has provided 62% of the revenues of these groups. At the same time, they are not viable without a steady stream of volunteer labor. More than 130,000 hours were donated this past year. There are intrinsic limits to the current dependency on unpaid labor and contributions made by private charity and local government which will eventually require increased support and intervention at the state and federal levels.

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INTRODUCTION

Dozens of new nonprofit community-based service organizations have formed in response to the AIDS epidemic. The focus of numerous others throughout the country has expanded or changed. Many of these groups were formed by leaders and concerned members of the gay community, which has suffered the greatest losses of any identified risk group in the population. Created largely to provide support services for persons with AIDS and to disseminate public health information, these groups have played a major role in responding to the epidemic. In the fall of 1984, a survey of 55 cities conducted by the United States Conference of Mayors reported that 60 percent of local health departments had established working relationships with community-based organizations providing a range of AIDS-related services.[1]

The role of the nonprofit sector in the provision of health and human services has come under increasing scrutiny in recent years.[2,3,4,5] The nonprofit sector has served to cushion the effects of government cutbacks and, at the same time, has experienced a decline in public funding itself. This paper examines the more limited question of the role of nonprofit community-based services in response to the epidemic in San Francisco which has experienced the second largest AIDS caseload in the world (next to New York City). In particular, it analyzes in detail the three largest community-based AIDS organizations in San Francisco: the Shanti Project, the San

Francisco AIDS Foundation and Hospice of San Francisco. Discussion focuses on the historical origins of these groups, the relationship to local government, the services they provide and their financial status. The data collected is based on audited and unaudited financial statements, internal documents, interviews with organizational personnel, and contracts between these organizations and the City and County of San Francisco. The economics of these organizations are analyzed with particular attention to the issue of donated labor, which has played a central role in these and similar groups around the country. Finally, the financial implications of community-based services for government health care expenditures are examined as they relate to the AIDS epidemic.

HISTORY

Local government has played a major role in organizing and funding a response to the AIDS epidemic in San Francisco. A confluence of political, economic, social and public health factors helped to shape this response.* The total number of reported AIDS cases in San Francisco grew dramatically from 24 in 1981 to 1,631 through the end of 1985.[6] In 1982, the San Francisco Department of Public Health (SFDPH), through its Office of Lesbian and Gay Health, began to coordinate efforts to plan and develop services to meet the growing demands that the epidemic placed on the health care system. To avoid duplication of services and to coordinate the City and County's response (hereafter referred to as the City), a separate AIDS Activity Office was established within the SFDPH in 1983 to:

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*Arno PS, Hughes RG: Local policy response to the AIDS epidemic: New York and San Francisco. Paper presented at the annual meetings of the APHA, Washington, DC: November 18, 1985.

- better coordinate and link the services related to the AIDS epidemic;
- identify service gaps and develop plans for addressing these needs;
- oversee, monitor and support AIDS-related contract services;
- anticipate funding requirements and justify new funding requests; and
- develop and maintain the Department's liaison with external funding and service agencies, community groups and education programs.[7]

The City has provided a level of funding for a wide range of AIDS-related services unmatched anywhere in the country. Funds have been allocated for epidemiological surveillance, assessments for medical care, homecare, housing, psychosocial counseling, professional education, public health education and risk reduction activities. Approximately $7.4 million in local funds were spent during Fiscal Year (FY) 1984-85 (July 1, 1984-June 30, 1985). $8.8 million is projected for FY 1985-86. [7]

The City chose to contract a number of services to community-based organizations, particularly public health education, risk reduction strategies, psychosocial counseling and home health care services, rather than to provide them itself. City funds provide a substantial percentage of the total revenues required by AIDS-related nonprofit groups.

San Francisco AIDS Foundation

The San Francisco AIDS Foundation (SFAF) was founded in April 1982 as a direct response to the AIDS epidemic. It began as an all-volunteer, grassroots organization composed mainly of gay community leaders and physicians. Initially located in a storefront with a single phone, the group set up an Information and Referral Hotline that soon became nationally known as a source of accurate information on AIDS.

Beginning in October of 1982 and continuing to the present, the SFAF formally contracted with the San Francisco Department of Public Health (SFDPH) to provide educational services in San Francisco. These services include educational events, telephone services, materials development and providing the media with accurate information on AIDS. In November 1983, the foundation contracted with the State of California, Department of Health Services to provide information and referral services and educational programs to other counties in Northern California. The foundation established a social services department in 1983 to assist persons with AIDS and related conditions in need of emergency services such as shelter, financial assistance and medical attention.

The Shanti Project

The Shanti Project was founded in 1974 by Dr. Charles Garfield, a research psychologist for the Cancer Research Institute at the University of California, San Francisco. It began as a nonprofit community-based organization whose goal was to deal with the problems of death and dying and provide free grief-counseling services to people with life-threatening diseases and their friends, families and survivors. In the fall of 1981, on the verge of bankruptcy, Shanti's Board of Directors resigned and the organization was temporarily held together by its volunteer staff. At this time its focus shifted to the AIDS epidemic. In December 1982, Shanti entered the first in a series of contracts with the SFDPH to provide counseling services and a housing program for persons with AIDS. This contract has continued through the present.

Hospice of San Francisco

Hospice of San Francisco (Hospice) was formed in 1978 as a nonprofit corporation to provide physical, emotional and spiritual care for terminally ill patients and their families in San Francisco County. In July 1983, it merged with two other existing nonprofit health care providers, the San Francisco Home Health Service (SFHHS) and the

Visiting Nurse Association of San Francisco (VNA). Hospice is a subsidiary of its parent corporation, now known as the Visiting Nurse Association of San Francisco.

Hospice first became involved with AIDS in early 1983 when it handled referrals for homecare and hospice services for AIDS patients. In response to requests for proposals from members of the San Francisco Board of Supervisors in March 1983, SFHHS and Hospice, in cooperation with the VNA, submitted a proposal to augment their existing direct home health care services and hospice programs. The VNA contracted with the SFDPH in September 1983. Problems arose immediately with the fee-for-service reimbursement policy under the terms of the contract, especially with regard to receiving adequate funds for home attendant care. By July 1984, a new contract was negotiated directly with Hospice to provide home health and hospice care to persons with AIDS. Under the terms of this contract, financing is per project rather than on a fee-for-service basis.

SERVICES PROVIDED BY ORGANIZATIONS

Emotional Support/Counseling

The psychosocial needs of AIDS patients are extensive, complex and unique.[8,9,10] Persons with AIDS and AIDS Related Complex (ARC) are typically young men in the prime of their lives who were recently in good health and are poorly prepared to suddenly face a life-threatening illness. Over 90 percent of all AIDS patients in San

Francisco are between the ages of 20 and 49.[11] An AIDS diagnosis is a terrifying experience that raises a number of difficult issues that an AIDS patient must immediately face. These include reactions of employers, families and friends, treatment options, sexual behavior modification, community fear and ostracism, financial hardship, physical deterioration, depression, and the fear of death itself.[12] Traditional health care systems have been unable or unwilling to develop an integrated approach to these areas of concern and have thus become the major focus of counseling interventions by community-based groups.

Emotional support and counseling services are provided by the Shanti Project whose trained professional and nonprofessional community volunteers offer free long term counseling to persons with AIDS, their sexual partners and their families. All counseling is done individually thus far, but the organization is also considering using a group counseling approach. Clients are matched to their counselors within 48 hours of their initial request. The meetings may take place at the client's home, the hospital or outpatient clinic or any other agreed-upon setting and they occur as frequently as is mutually suitable. During FY 1984-85, Shanti provided more than 56,000 hours of emotional support counseling to people affected by AIDS in San Francisco (Table 1).

At San Francisco General Hospital, the only acute-care municipal hospital in the city, more than 6,000 hours were spent counseling AIDS patients and their visitors. This inpatient counseling program assists patients in planning their discharge, and attempts to meet their psychosocial needs in areas ranging from dealing with the hospital staff to coping with impending death, removal from life-support systems and potential suicide.

Practical Support

AIDS is a progressively debilitating disease which causes both functional impairment and physical dependency upon others.[13] At intermittent points throughout the disease cycle, normal activities such as cooking, cleaning, doing the laundry, shopping and getting from one place to another become extremely difficult. The practical support programs of the Shanti Project and Hospice provide volunteers to help with these normal day-to-day activities. During FY 1984-85, Shanti and Hospice provided nearly 17,000 and 2,000 hours, respectively, of practical support.

Home-Based Hospice Care

As discussed above, treating devastating AIDS-related infections often requires acute medical interventions in a hospital. However, during the course of the disease including the final days before death, there may be periods of time when hospital care is unnecessary and treatment at home desirable. Intermittent nursing and social work visits are inadequate to meet the multiple physical and psychosocial needs discussed earlier.* In addition, traditional home care under the Medicare structure generally does not meet the intense needs of persons disabled with AIDS because most patients are not eligible for Medicare.

Hospice's AIDS Home Care program has organized a multidisciplinary team to provide health monitoring, skilled nursing and other home health services which enable AIDS patients to maintain themselves at home. This team is comprised of registered nurses, medical social workers, home attendants (home health aides and homemakers) and volunteers with contract services from physicians, therapists and licensed vocational nurses when necessary. A broad range of services is available for those living independently and those in the terminal stages of their illness. During FY 1984-85, Hospice provided 7,764 days of home care to 165 different persons with AIDS (averaging 47 days per person).

Housing Services

Housing has been a particularly acute problem for persons with AIDS throughout the country.[14,15] Persons with AIDS have been displaced from their homes either because of financial difficulties relating to the burden of catastrophic illness or because of discrimination by landlords, family or friends fearful of contagion. This problem has been less severe in San Francisco, where predominantly white middle class gay men have been affected, than in other parts of the country. In New York City, where the housing vacancy rate is extremely low and a greater proportion of persons with AIDS are poor, black and intravenous drug users, the housing status of afflicted persons is more transient, even prior to becoming ill.

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* Martin JP, Schietinger H, Pratt S, Titus G: A model for providing comprehensive community-based care to people with AIDS; an alternative to institutional care. Paper presented at the annual meetings of the APHA, Washington, DC: November 18, 1985.

Nevertheless, by early 1983, increasing numbers of persons with AIDS were losing their homes and the Shanti AIDS Residence program was established. This program operates low-cost independent housing for San Francisco residents with AIDS. Each tenant has a private bedroom and cooperatively runs the Residence. Although no direct health care services are provided by Shanti, home health care is available at the Residence through Hospice and other community providers. Shanti currently administers eight of these Residences. During FY 1984-85, 87 persons spent a total of 7,046 days in a Shanti Residence (averaging 81 days per person).

While long-term housing is handled by Shanti, emergency housing is provided by the San Francisco AIDS Foundation to persons with AIDS/ARC who have been displaced from their homes. Housing is available for up to two weeks during which time social workers assist clients in finding permanent housing.

Public Health Education

In lieu of a vaccine, which could be many years away, effective public health education is the best known method to curb the transmission of AIDS. This includes disseminating information to high risk groups about safe sex practices and the dangers of needle sharing and promoting health activities that bolster the immune system, such as better nutrition, stress reduction and exercise. The population outside the main risk groups needs information on transmission of the disease in order to reduce unwarranted fears, promote support for effective programs and prevent further spread of the epidemic.

The paucity of federal resources devoted to public education efforts is of particular concern. During FYs 1984 and 1985, less than four percent of all U.S. Public Health Service AIDS funds were appropriated for information dissemination/public affairs.[16] Thus, much of the burden for providing public health education has been placed on local governments and community-based groups around the country.[1]

In San Francisco, public health education is largely the province of the AIDS Foundation, which works closely with the SFDPH, university scientists and market researchers. Although initially focused on gay men, the foundation has expanded its target groups to include others at risk for AIDS, the general public and health care practitioners. There are five components to the education program at the AIDS Foundation: telephone services, educational events, media advertisements, media relations and material development and distribution (Table 2).

A telephone hotline and a variety of educational events provide the public basic information about AIDS (such as symptoms, risk reduction guidelines, infection control precautions, treatment protocols and side effects). Telephone referral services are also offered to physicians, screening clinics and other organizations. Advertisements reach large numbers of people through the print and electronic media. In addition, considerable effort has been spent working with the media to ensure accurate reporting of the epidemic. The final component of the AIDS Foundation's educational services is developing and distributing detailed and informative brochures, flyers and videotapes.

Social Services

Access to government programs has been facilitated by the social services program at the AIDS Foundation. Social workers act as liaisons between persons with AIDS and government bureaucracies at the Social Security Administration, General Assistance and Food Stamp programs to ensure efficient application for benefits when necessary.

A privately funded food bank at the AIDS Foundation provides groceries for those in financial need. Disability benefits are the sole source of funds for many persons with AIDS/ARC. The food bank provides eligible persons with a weekly bag of groceries worth $25-30. At the present time, approximately 150 people use this service each month.

FINANCIAL STATUS OF COMMUNITY-BASED GROUPS

Local government in San Francisco has provided a substantial base of financial support to these community-based groups. During FY 1984-85, the City funded an average of 62 percent of the total revenues of the Shanti Project, the AIDS Foundation and Hospice. A more detailed picture of these groups' financing is given in Table 3.

The second largest source of funding is private donations, which average 29 percent of total revenues for the three groups. These come primarily from individual donors and fundraising events and to a lesser extent from local business and foundation contributions.

This pattern of funding differs from non-AIDS related community groups in San Francisco . According to a recent study* of nonprofit health care organizations (exclusive of hospitals) in the San Francisco Bay Area, only 10 percent of revenues came from private donations. 40 percent came from government sources, primarily at the state and federal level.

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*Urban Institute: The Nonprofit Sector Project, Washington, DC: unpublished data, 1985.

It is worth noting that only Hospice, the most traditional health care provider of the three groups, suffered a net loss last year. Because it relies on third party payers, particularly Medi-Cal and private insurers, who have been unwilling to reimburse home-based hospice care for AIDS patients adequately. Hospice wrote off more than $57,000 in uncollected bills (Table 4). Its net loss for the year ($30,000) could easily be expunged by improved reimbursements from third party payers. In fact, as of January 1986, the lack of adequate reimbursements from Medi-Cal, Medicare and private insurance has forced the non-AIDS component of Hospice (which is not subsidized by the City) to place a moratorium on accepting new terminally ill patients into its program.[17,18]

A comprehensive analysis of the viability of these organizations and the range of services they provide must include more than a narrow fiscal review of their expenses and revenues. Of fundamental importance to the survival of these groups is their extensive use of volunteer labor.

VOLUNTEER PROGRAMS

Volunteers provide the backbone of services performed by most community-based AIDS organizations throughout the country. In the US Conference of Mayors' 55 city survey, nearly 80 percent of services provided by these groups were carried out by volunteers.[1] In San Francisco, the AIDS Foundation and the Shanti Project rely heavily on donated labor. Hospice employs primarily paid staff.

In Table 5, the magnitude of donated labor is reflected in the huge number of monthly volunteer hours, as well as in the ratios of donated to paid labor. The outpouring of support from the community to AIDS groups far exceeds the support given to other nonprofit organizations in the San Francisco Bay Area.

The sizable contribution of volunteers to these organizations and to the community can also be viewed in economic terms. In Table 6, upper and lower bound estimates are made of the economic values attributed to donated labor. The substantial economic valuations of unpaid labor represent a range of 30 to 84 percent of the total annual dollar expenditures for the Shanti Project and 15 to 36 percent of expenditures for the AIDS Foundation.

The AIDS Foundation and the Shanti Project provide two different organizational models for the use of volunteers. At the AIDS Foundation, volunteers are seen as "staff extenders" : The paid professional staff is primarily responsible for the activities of the Foundation and volunteers assist them in carrying out their activities. At the Shanti Project volunteers provide the bulk of services themselves, once they are adequately trained. The following sections describe more precisely the roles volunteers play in these organizations and the training requirements involved.

Shanti Project

Emotional Support Program

Volunteers in the Emotional Support Program offer free counseling to people with AIDS and their sexual partners, friends and relatives. Volunteers provide counseling for bereavement as well as coping with the illness and meet clients in their home, hospital or other agreed-upon setting. In addition to counseling, they offer practical help such as hospital advocacy, financial and legal resources, establishing and maintaining support services at home and arranging funeral and memorial services.

Volunteers must submit an application and be interviewed before being accepted for a 44 hour training. This training program, which was developed during the 11 years of the Shanti Project's existence, was modified when the organization's focus shifted to AIDS. It now includes overviews of the medical and psychological aspects of AIDS, substance abuse modification techniques, grief counseling specific to AIDS, alternative therapies and information on the services of other AIDS provider organizations. At the completion of the training, the volunteers make a commitment of 6-8 hours weekly for 6 months. For two of these hours they participate in a support group that meets biweekly, where they receive feedback, guidance and support.

Practical Support Program

Practical Support volunteers assist with the everyday practical needs of people with AIDS such as cooking, shopping, house cleaning and transportation. Some of the volunteers assist the nursing staff at San Francisco General Hospital's outpatient ward, while others participate in the Residence Program by moving furniture and doing the ongoing maintenance and house cleaning.

Like the Emotional Support volunteers, they must apply and be interviewed before being accepted into the training program. Their mandatory 22 hour training includes an AIDS medical overview, basic training on lifting and physically assisting compromised persons, group dynamics, assessing suicide risks and evidence of substance abuse that requires referrals and use of role-playing to develop the necessary skills for helping clients. The volunteer's commitment after this training is also for 6-8 hours weekly for 6 months and includes participation in a biweekly support group.

Information and Referral

Office volunteers in this program handle requests for information and referrals about test sites, symptoms, anxiety counseling and the services offered by the Shanti Project and other AIDS provider organizations. They also staff the Project's Speaker's Bureau, which supplies city and community agencies with free speakers on the psychosocial aspects of AIDS.

San Francisco AIDS Foundation

Volunteers work in all programs of the San Francisco AIDS Foundation. Forty percent of volunteer hours are spent staffing the telephone hotline which disseminates basic information on AIDS and makes referrals to specific AIDS programs and to appropriate physicians. The hotline training program includes education in basic medical information and other topics that are likely to arise in calls and active listening skills. After the training, the volunteers are given a post-test and routine refresher sessions to keep their information up to date. Staff members and outside consultants periodically call the hotline to monitor the information being disseminated.

Volunteers also work providing office support in general administration, planning educational events, development and distribution of materials, social services and the food bank.

Hospice of San Francisco

Hospice of San Francisco enlists the services primarily of two kinds of volunteers: Patient Care Volunteers and Volunteer Massage Therapists. The Patient Care Volunteers provide in-home supportive services for AIDS patients and their families and friends. These services include cooking, shopping, transportation, light housekeeping, gardening, visiting, sitting with patients, and providing respite for their families. In the Hospice office, volunteers do clerical work and assist in fund raising.

These volunteers go through a 16 hour training to orient them to basic hospice care and specifically for the care of AIDS patients. They are recruited and trained by the Volunteer Coordinator and attend weekly support groups. Home visits are supervised by the professional staff. In addition to this basic 16 hour training, massage therapists, who are licensed practitioners, receive 30 hours of training in massage therapy, much of which is geared specifically to massage techniques for AIDS patients. All volunteers commit three to ten hours of their time per week for a minimum of one year.

DISCUSSION

The data presented above clearly indicate the indispensable role volunteers play in these AIDS organizations and the contribution they make to their community. Despite the base of financial support provided by local government funding and charitable donations, these organizations-- with the exception of the Hospice program--are not viable without a continuous supply of unpaid labor. This raises a number of important issues.

Can the supply of people willing to donate their time and energies to the needs of those affected by AIDS match the expected growth of the epidemic? This question is crucial in areas of both high and low disease incidence. In New York and San Francisco, where AIDS has been concentrated and service demands have been the greatest, the pool of volunteers are generally drawn from the large, well-organized gay communities. However, it is logical to assume that the level of volunteer support will at some point reach its limit. Furthermore, there are indications that the number of new AIDS cases among gay and bisexual men has begun to level off at least in New York and San Francisco. At the same time, the proportion of IV drug related AIDS cases continues to rise. This reveals a potential flaw in a system so heavily dependent upon volunteer labor. While the gay community has done an extraordinary job thus far in supporting its afflicted members in addition to caring for those in other risk groups, it is unclear whether this level of voluntarism will be maintained if the proportion of AIDS cases among gay men declines significantly.

Recent evidence suggests that the epidemic is currently spreading faster outside the concentrated areas than within them. [19] In these low-incidence regions there may not be a significant at-risk population from which to draw a large pool of volunteers. Gaps in services which already exist in many of these communities may become more severe as the epidemic progresses. Some cities have not only failed to provide adequate services but have shipped AIDS patients to San Francisco and other large metropolitan areas for treatment. [20,21]

Despite the invaluable contributions made by volunteers, many of the services needed by persons with AIDS can only be provided on a continuing basis by professionals. These include major aspects of hospital care, mental health and social services. Persons with AIDS are as entitled to treatment by health care professionals as anyone with a debilitating and fatal illness.

Although Shanti, the AIDS Foundation, and to a lesser extent, Hospice rely upon a large supply of unpaid labor, they also depend on substantial financial support from local government and private sources. These funds have been used to build and maintain organizational structures with paid staff who recruit, train, supervise and support the volunteers. Other cities have expected volunteers to provide the bulk of these services themselves without a base of financial support, thus weakening their efforts and threatening the long-term viability of the organization. In San Francisco, local government has provided generous support during the early 1980s, a period of economic prosperity and a surplus in the City budget. It is also a city with a politically powerful gay community and may be less homophobic than elsewhere. The budget surplus has now dwindled and it remains to be seen how long the City will continue to fund the expansion of community-based services to meet the needs of a still growing epidemic.

It has been argued that investing public funds in community-based services not only affords better quality care for persons with AIDS, but is also cost effective.[22,23] The fiscal argument rests primarily on two factors: 1) the hidden subsidy of large quantities of unpaid labor (volunteers) allows for a greater production of services per dollar expended than is possible if the City provided the services itself and 2) the availability of community-based services is linked to reductions in the length and expense of hospitalizations for AIDS patients.

Reducing the overall rate of hospitalization at San Francisco General Hospital (SFGH) has a direct financial impact on the City and County of San Francisco. SFGH, a municipally owned facility, has played a central role in inpatient and outpatient care of AIDS patients in San Francisco. In 1984 and earlier, SFGH cared for approximately one-half the AIDS inpatient caseload in the city. This was reduced to a one-third during 1985.* Moreover, reimbursements by third party payers (public and private) do not fully cover the cost of providing services to AIDS patients and at least one-quarter of the patients have no health insurance coverage at all.** As a result, local government tax revenues subsidize uncompensated care. Community-based services, which provide alternatives to costly hospitalizations, have thus been both rational fiscal policy and in the interests of patient care.

Outpatient services for AIDS patients have been available at SFGH since September 1981 and at the University of California in San Francisco (UCSF) since August 1984. During 1985, the AIDS clinics at SFGH and UCSF averaged approximately 1,000 and 100 visits per month respectively.[7] Outpatient services, particularly at SFGH, have undoubtedly played an important role in reducing the overall level of hospitalization in San Francisco. Between January and June 1985, the average length of stay for AIDS patients in in San Francisco hospitals was 12 days.* This compares to stays of 17 days in Los Angeles,[24] 31 days in Philadelphia[25] and 25 days in New York City.[26]

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*San Francisco Mayor's Advisory Committee on AIDS, unpublished minutes, 1985.

**West Bay Hospital Conference: Monthly AIDS Hospital Utilization Report, unpublished data, October 25, 1985.

Furthermore, outpatient and inpatient services at SFGH are integrated with those provided by community-based groups. For example, counselors from Shanti, Hospice and the AIDS Foundation work in the hospital itself and help patients shorten their length of stay by arranging care for them outside the hospital. Hospital costs and length of stay are also reduced by the relatively low utilization of costly intensive care facilities at SFGH. Only 11 percent of SFGH's AIDS admissions spent one day or more in intensive care during 1984, which is probably lower than in other cities.** This may reflect the role of Shanti counselors in educating patients about the course of their illness and the efficacy of technological interventions in its terminal stages.

Finally, the housing and home-based hospice care provided by community-based groups is far less expensive than inpatient hospitalization. In contrast to the ambiguous findings of other studies that measure the cost effectiveness of hospice care around the country (for a review of these studies see ref. 27), the home-based program of Hospice of San Francisco provides unequivocal results. For the 165 AIDS patients served by Hospice during FY 1984-85, the average cost per day was $94 and the total average cost per patient was $4,401. The Scitovsky study reported the average cost of hospitalization for AIDS patients at SFGH per day was $773, the average cost per hospitalization was $9,246 and the total lifetime cost for those patients who received all their hospital care at SFGH was $27,857. Hospitalizing AIDS patients is obviously necessary at times, particularly for acute medical episodes and intensive medical supervision but often is unnecessary if patients can live where suitable home health care and social support services are available.

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*West Bay Hospital Conference: Monthly AIDS Hospital Utilization Report, unpublished data, October 25, 1985.

**Scitovsky AA, Cline M, Lee PR: Medical care costs of AIDS Patients treated in San Francisco. Paper presented at the annual meetings of the APHA, Washington, DC: November 19, 1985.

CONCLUSIONS

Community-based organizations have played a key role in responding to the AIDS epidemic. They have provided an important and otherwise missing dimension to patient care and social support services and have been instrumental in developing and disseminating public health information and prevention strategies. The marked drop in other sexually transmitted diseases among gay men in San Francisco[19] and the reported decline in high-risk sexual behavior associated with enhanced transmission of the AIDS virus [28] is undoubtedly due to some extent to the educational efforts of these groups.

It is argued that local government support of these community organizations is a rational fiscal response which helps to reduce the overall economic impact of the epidemic. However, this is based on the hidden subsidy of a large supply of unpaid labor from the community. In the past, health care expenditures were subsidized to a great extent by shifting the costs to public and private third party payers. In the current era of increased competition, prospective reimbursement and pervasive attempts at cost containment, this has become increasingly difficult. The donations made by a large body of unpaid labor represent the final cost shift. If the epidemic continues to grow unabated there are intrinsic limits to the contributions made by local government, private charity and unpaid labor. Under such conditions, pressures on local health care systems will mount, requiring substantial financial intervention at the state and federal levels.

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TABLE 1--Social Support and Counseling Services Provided by Community-Based Organizations: San Francisco, Fiscal Year 1984-85 (July 1- June 30)

Program	*Units Provided**	*People Served*	*Units per Person*
Shanti Project			
Emotional Support	56,539	950	56
Practical Support	16,777	248	68
Inpatient Counseling (SF General Hospital)	6,138	1,260	5
Hospice			
Practical Support	1,820	n/a	n/a

* Counseling Units: number of hours spent in contact with clients - both individually and in groups - and in conference with staff/volunteers about specific client business.

TABLE 2--Educational Services Provided by Community-Based Organizations: San Francisco, FY 1984-85

	*Units Provided**	*People Served*
AIDS Foundation		
Telephone services	9,968	9,470
Educational Events	128	11,500
Media Relations	507	n/a
Media Advertising	17	n/a
Materials Development & Distribution	240,872	n/a
Shanti Project		
Information & Referral	23, 073	n/a

*Telephone Service Units: number of telephone calls received (San Francisco only).

Educational Events Units: number of forums, workshops and speaking engagements delivered.

Media Relations Units: number of media contacts about discrete issues with print and electronic media.

Media Advertising Units: number of original advertisements developed for placement.

Material Development/Distribution Units: number of pieces of literature distributed.

Information & Referral Units: number of telphone calls received, letters answered and attendees at workshops and forums

TABLE 3-- Financial Status of Community-Based AIDS Organizations in San Francisco: Fiscal Year 1984-1985

	AIDS Foundation	*Shanti*	*Hospice*
Total Program Expenditures	$1,094,928	$ 961,863	$726,179
Total Revenue	$1,245,182	$1,056,115	$696,212
Net Income (Loss)	$150,254	$94,252	($29,967)
Percentage Total Revenue by Source:			
City & County of SF	59%	60%	68%
State of CA			
grants	7	--	--
Medi-cal	--	--	5
Dept. of Social Services	--	--	3
Federal			
grants	5	--	--
Medicare	--	--	1
Private Contributions	29	40	13
Private insurance	--	--	8
Patient Fees	--	--	2
Total	100	100	100

Data is based on audited finanical statements for the Shanti Project and unauadited financial statements for Hospice of San Francisco and the AIDS Foundation.

TABLE 4--Hospice of San Francisco, Bad Debt By Source: Fiscal Year 1984-85

	Bad Debt Dollars[*]	*% Expected Revenue*[**]
Private Insurance	$38,304	39.8%
Medi-Cal	17,605	32.5
Medicare	500	10.3
Other	876	--
Total Bad Debt	**$57,285**	**7.6%**

* Indicates uncollectible billing by source.

** Indicates the percentage of total billing that is uncollectible by source.

TABLE 5-- Community-Based Organizations, Staff Hours: San Francisco, Fiscal Year 1984-85

	Volunteer Staff Avg. Total Hours/Month	Paid Staff Avg. Total Hours/Month	Ratio Vol./Paid hrs.
S.F. AIDS Foundation	3,807	1,976	1.93
Shanti Project	6,852	3,900	1.76
Hospice	349	7,193*	0.05
All Non-Profit** Organizations S.F. Bay Area	690	1,725	0.40

* Approximately 40% of the paid staff hours in the Hospice program is provided by home health aides and homemakers.

**This data is shown for comparative purposes and is based on a sample of 366 non-profit organizations in the San Francisco Bay Area during 1982.
Source: Ref. 3.

TABLE 6--Economic Value of Donated Labor, Community-Based AIDS Organizations: San Francisco, FY 1984-85

	No. Volunteer Hrs.	Rate$_1$*/Hr.	$ Value	Rate$_2$**/Hr.	$ Value
Shanti Project					
Emotional support/ counseling	56,539	$3.35	$189,406	$11.50	$650,199
Practical support	16,777	3.35	56,203	6.00	100,622
Info. & referral	910	3.35	13,049	8.25	7,507
AIDS residence	8,000	3.35	26,800	6.00	48,000
TOTAL	**82,226**		**285,458**		**806,328**
SF AIDS Foundation					
General admin.	2,990	3.35	10,017	8.25	24,668
Hotline	18,130	3.35	60,736	8.25	149,573
Educ. events	5,490	3.35	18,392	8.25	45,293
Material devpt/dist.	4,510	3.35	15,109	8.25	37,208
Social services	6,240	3.35	20,904	8.25	51,480
Food bank	8,320	3.35	27,872	8.25	68,640
TOTAL	**45,680**		**153,030**		**376,862**

TABLE 6 (cont.)

	No. Volunteer Hrs.	Rate$_1$*/Hr.	$ Value	Rate$_2$**/Hr.	$ Value
Hospice* **					
Massage therapy	600	15.00	9,000	25.00	15,000
Patient care	1,820	3.35	6,097	6.00	10,920
General admin.	720	3.35	2,412	8.25	5,981
TOTAL	**3,140**		**17,509**		**31,901**
GRAND TOTAL	**131,046**		**455,997**		**1,215,091**

* Rate$_1$ provides a lower bound hourly rate for donated labor. The minimum wage ($3.35/hour) is used for all programs except massage therapy which is provided by certified practitioners.

**Rate$_2$ provides an upper bound estimate (which may be conservatively low). These rates were derived as follows: emotional support counseling was pegged at the prevailing hourly rate for social workers used by the Hospice program; volunteers in the practical support and AIDS residence program at Shanti and patient care at Hospice were pegged to the prevailing rate for home attendant care; all positions at the AIDS Foundation, at the information and referral program at Shanti and general administration at Hospice were pegged to an entry level secretarial position in San Francisco.

***The Hospice program began in October, 1984.

Appendix

AIDS Funding
City & County of San Francisco

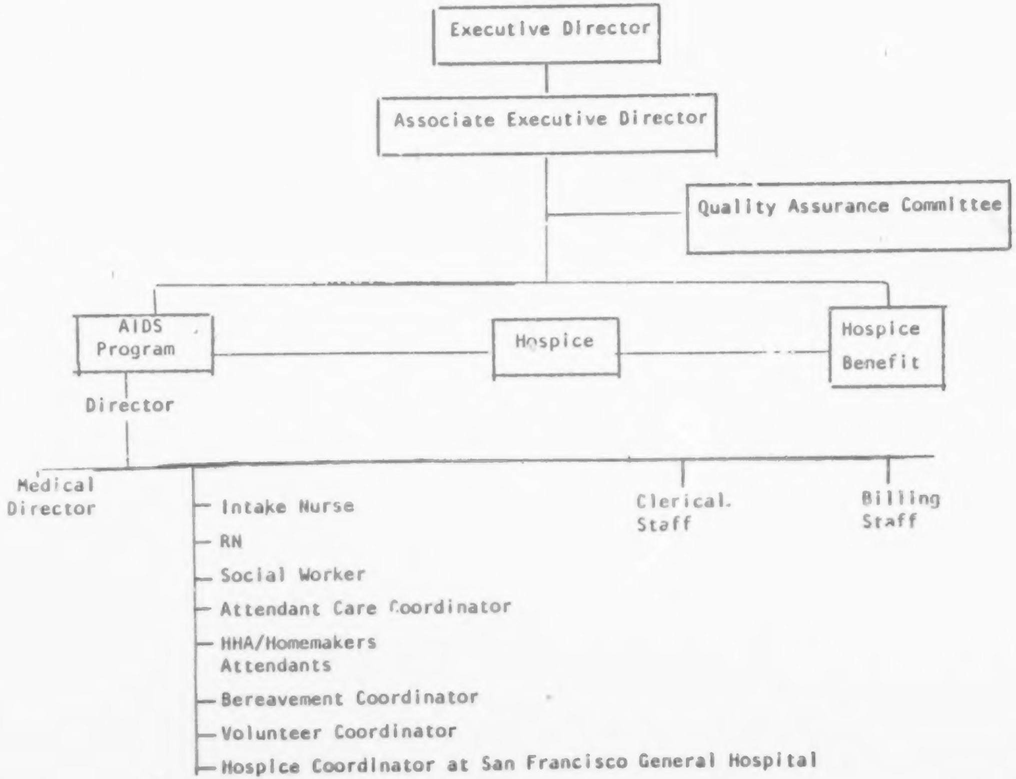
SUMMARY OF FUNDING - ALL SOURCES - FY 1985-86

Programs	Local	State	Federal
Labs and Epidemiological Support		- 0 -	
Monitoring and Case Finding	$ 436,381		$ 300,000
Enteric Pathogen Screening	360,988		
Epidemiological Studies	20,164		800,000
AIDS Laboratory	111,950		
Assessments and Medical Care		(?)	(?)
AIDS Screening	$ 268,139		
Outpatient Clinics	1,818,507		
Inpatient Services	1,772,829		
Extended Care Facility	271,420		
Intermediate Care Facility	222,000		
Home Health Care	1,141,414		
Other Support for PWAs		- 0 -	- 0 -
Emergency Housing and Social Service Advocacy	$ 291,750		
Long Term Housing	359,205		
Emotional Support	161,294		
Practical Support for Daily Living	151,793		
Emotional Support and Advocacy/ San Francisco General Hospital	168,285		
Mental Health Support/SFGH	69,051		
Substance Abuse Services	58,182		
Professional Education			- 0 -
Mental Health Service Providers	$ 43,784	$ 53,700	
Substance Abuse Service Providers	76,759	36,378	
Enteric Pathogens	39,150		
Health Care Providers	(See Educ. Events)	74,352	
General Education and Risk Reduction Activities			
Media Advertising	$ 111,604	$ 137,565	
News and Feature Stories	70,735	16,250	
Pamphlets and Collateral Materials	72,990	98,670	
Telephone Information and Referral Services	62,208	46,039	
Educational Events	72,251	76,865	
Alternative Test Sites Program	5,930		$ 971,521
Peer Group Support	319,445	65,230	
Administration/Coordination	$ 259,684	$ 61,591	
TOTAL (10/8/85)	$8,817,892	$ 666,640	$2,071,521

SUMMARY OF FUNDING - ALL SOURCES - FY 1984-85

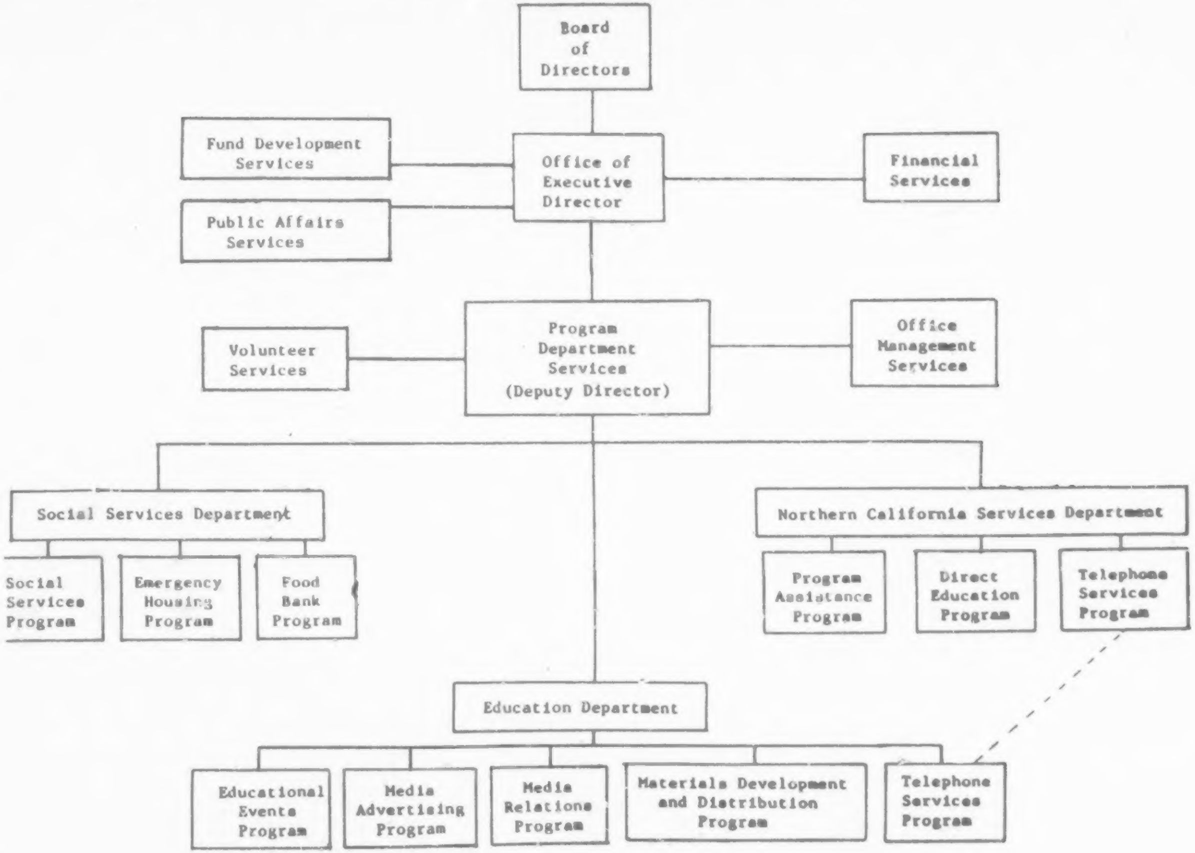
Programs	Local	State	Federal
Labs and Epidemiological Support		- 0 -	
Monitoring and Case Finding	$ 393,334		$ 145,000
Enteric Pathogen Screening	368,961		
Epidemiological Studies	16,083		365,000
AIDS Laboratory	93,292		
Assessments and Medical Care		(?)	(?)
AIDS Screening	$ 260,019		
Outpatient Clinics	1,557,667		
Inpatient Services	1,575,928		
Extended Care Facility	357,000		
Intermediate Care Facility	- 0 -		
Home Health Care	712,371		
Other Support for PWAs		- 0 -	- 0 -
Emergency Housing and Social Service Advocacy	$ 170,999		
Long Term Housing	234,637		
Emotional Support	136,235		
Practical Support for Daily Living	98,032		
Emotional Support and Advocacy/ San Francisco General Hospital	138,689		
Mental Health Support/SFGH	97,707		
Substance Abuse Services	12,955		
Professional Education		- 0 -	- 0 -
Mental Health Service Providers	$ 16,750		
Substance Abuse Service Providers	38,863		
Enteric Pathogens	15,573		
Health Care Providers	(See Educ. Events)		
General Education and Risk Reduction Activities		- 0 -	
Media Advertising	$ 173,986		
News and Feature Stories	65,049		
Pamphlets and Collateral Materials	145,909		
Telephone Information and Referral Services	124,029		
Educational Events	132,804		
Alternative Test Sites Program			$ 188,554
Peer Group Support	281,740		
Administration/Coordination	$ 218,614		
TOTAL (10/8/85)	$7,437,226	$ - 0 -	$ 698,554

HOSPICE OF SAN FRANCISCO

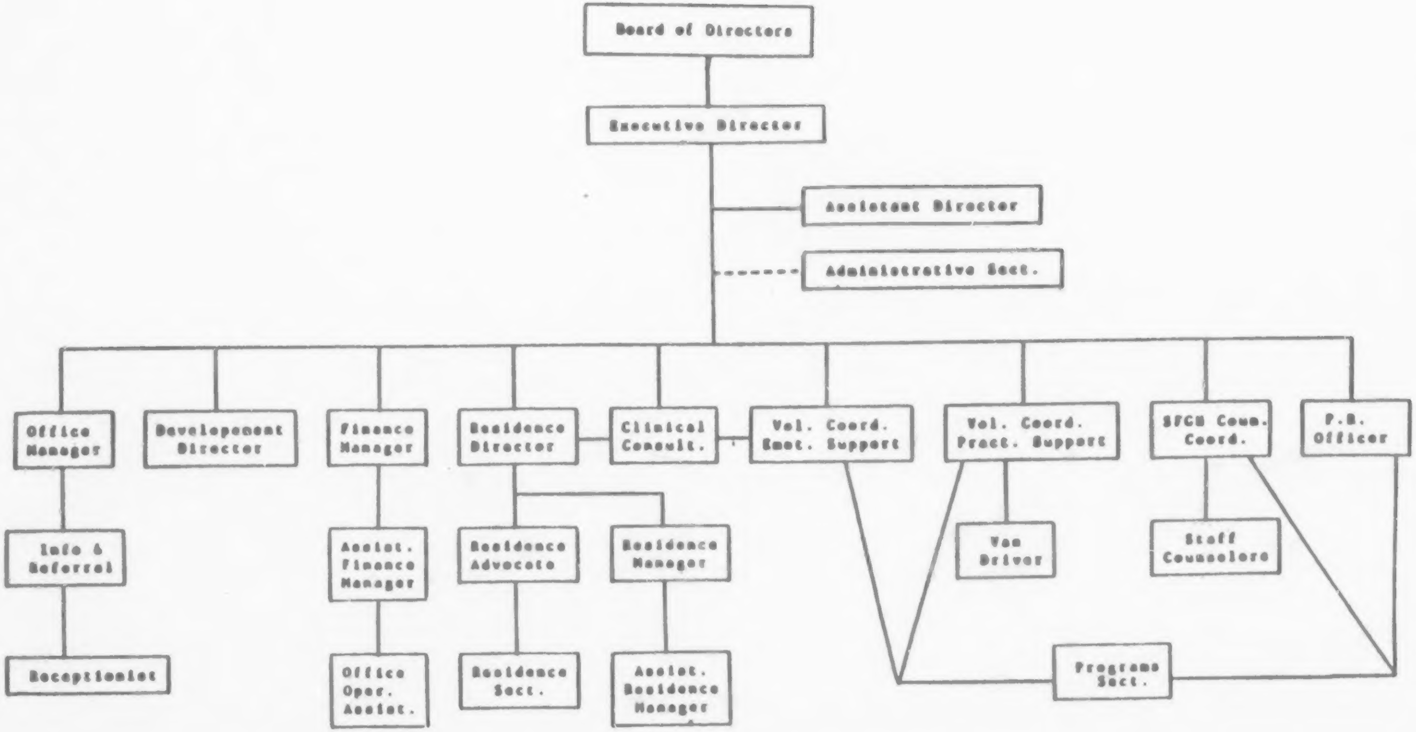

Executive Director
Associate Executive Director
Quality Assurance Committee
AIDS Program
Hospice
Hospice Benefit
Director
Medical Director
Intake Nurse
RN
Social Worker
Attendant Care Coordinator
HHA/Homemakers Attendants
Bereavement Coordinator
Volunteer Coordinator
Hospice Coordinator at San Francisco General Hospital
Clerical Staff
Billing Staff

7/85

ORGANIZATIONAL CHART OF THE SAN FRANCISCO AIDS FOUNDATION


Board of Directors
Fund Development Services
Public Affairs Services
Office of Executive Director
Financial Services
Volunteer Services
Program Department Services (Deputy Director)
Office Management Services
Social Services Department
Social Services Program
Emergency Housing Program
Food Bank Program
Northern California Services Department
Program Assistance Program
Direct Education Program
Telephone Services Program
Education Department
Educational Events Program
Media Advertising Program
Media Relations Program
Materials Development and Distribution Program
Telephone Services Program

SHANTI PROJECT ORGANIZATIONAL CHART


Board of Directors
Executive Director
Assistant Director
Administrative Sect.
Office Manager
Development Director
Finance Manager
Residence Director
Clinical Consult.
Vol. Coord. Emot. Support
Vol. Coord. Pract. Support
SFGH Coun. Coord.
P.R. Officer
Info & Referral
Receptionist
Assist. Finance Manager
Office Oper. Assist.
Residence Advocate
Residence Sect.
Residence Manager
Assist. Residence Manager
Van Driver
Staff Counselors
Programs Sect.

AIDS Services Referral Guide

Provided by the San Francisco Community Partnership on AIDS

Adult Immodeficiencies Clinic

400 Parnassus, # A555, San Francisco, CA 94143 (415) 666-3226
Provides and coordinates a complete range of health care services for persons with AIDS and AIDS-related conditions. In addition to routine health care and standard treatments, people can electively enroll (when eligible) in on-going research protocols.

The AIDS Health Project

333 Valencia Street, San Francisco, CA 94103 (415) 626-6637
Supportive health promotion program for people at risk for AIDS, and those with AIDS and AIDS related conditions. Provides low-cost educational support groups. No one will be turned away for lack of funds. These groups run for 8 weeks and are focused on various aspects of creating a healthier lifestyle, including AIDS prevention. The groups meet once a week for two hours.

AIDS Home Care Hospice Program

225 30th Street, San Francisco, CA 94131 (415) 285-5619
Mobilizes a multi-disciplinary team of skilled health professionals, dedicated para-professionals, and trained volunteers under the direction of a physician, to provide the needed support to manage a person with AIDS's care in the home during the final stages of life.

AIDS Interfaith Network

890 Hayes Street, San Francisco, CA 94117 (415) 928-HOPE
Provides spiritual support/counseling to persons with AIDS, their families, lovers and friends. Also provides education and training to the religious community at large regarding this crisis.

AIDS Screening Clinics

City Clinic - 356 7th Street, San Francisco (415) 864-8100
Health Center I - 3850 17th Street, San Francisco (415) 558-3905
Health Center II - 1301 Pierce Street, San Francisco (415) 558-2891
Provides evaluation for AIDS to concerned persons at high risk. The visit includes counseling, history taking, symptoms review and education by a Registered Nurse, and a detailed physical examination by a specially trained physician.

AIDS Services Referral Guide Page 2

Bay Area Lawyers for Individual Freedom

(415) 982-9211

Provides legal assistance to people with AIDS, their loved ones and those with legal problems related to AIDS.

Bay Area Physicians for Human Rights

P.O. Box 14546, San Francisco, CA 94114 (415) 673-3189

Provides gay-sensitive health care referral service for people in the greater Bay Area. BAPHR is the professional association for gay/lesbian physicians in the Bay Area and is actively involved in educational and political forums to promote more responsive and gay-sensitive health care throughout the medical system.

The Godfather Fund

c/oThe Tavern Guild
P.O. Box 11309, San Francisco, CA 94101 (415) 771-6133

Provides personal care items to people with AIDS and AIDS-related conditions.

Lyon-Martin Clinic Women's Health Services

2480 Mission St, Ste 214, San Francisco, CA 94110 (415) 641-0220

A non-profit medical clinic staffed completely by women providing quality general medical (primary) health care, gynecology, dermatology and internal medicine services, with special emphasis on lesbian health care. Also involved in the coordination and provision of supportive health care services for women who may be at risk for AIDS.

Mobilization Against AIDS

335 Noe Street, San Francisco, CA 94114 (415) 431-4660

Non-partisan polical action group organizing nation-wide to secure a better response from the government for AIDS funding for research, education and patient services. Also opposes the use of AIDS as a political weapon.

Operation Concern

1853 Market Street, San Francisco, CA 94103 **(415) 626-7000**
TTD (415) 626-7000

Offers individual and group psychotherapy, family therapy, special programs, and referrals to promote the emotional and social health of lesbians, gay men and their families.

People With AIDS San Francisco

c/o San Francisco AIDS Foundation
333 Valencia Street, San Francisco, CA 94103 **(415) 864-4376**

A group open to any person diagnosed with AIDS. Provides referrals, emotional support, recreation, and patient advocacy for persons with AIDS by persons with AIDS. Also works in conjunction with the SF AIDS Foundation in operating the "People With AIDS Switchboard", a service to help network and communicate with each other.

San Francisco AIDS Foundation

333 Valentia Street, San Francisco, CA 94103 **(415) 864-4376**

The San Francisco AIDS Foundation is a community-based agency which coordinates AIDS prevention education projects throughout the Bay Area and Northern California for the general public as well as people at high risk for AIDS. The Foundation also provides and coordinates direct social services, referrals, emergency housing, and food bank services for people with AIDS and ARCs in San Francisco.

AIDS Hotline

AIDS information, referral hotlines.

In San Francisco	**(415) 863-AIDS**
Toll Free Northern California	**(800) FOR-AIDS**
TTD	**(415) 864-6606**
People With AIDS Switchboard	**(415) 864-4376**

Foodbank for People with AIDS **(415) 864-4376**

Provides food staples as well as food discounts from retailers to people with AIDS and AIDS-related conditions. Food is donated by community organizations, businesses, and individuals. Drop-off points include the Community Thrift Store, International David Society, Castro Medical Clinic, Vibrant Health Center, and the San Francisco AIDS Foundation.

The San Francisco AIDS Fund

1547 California St, Ste B, San Francisco, CA 94109 **(415) 821-1230**

Provides limited direct cash assistance to people with AIDS in order to assist with financial emergencies.

AIDS Services Referral Guide Page 4

Shanti Project

890 Hayes Street, San Francisco, CA 94117 (415) 558-9644
Provides emotional support and practical support programs for persons with AIDS, their friends, lovers and family. Services include one-to-one counseling and support groups, as well as non-counseling practical support such as transportation, shopping, and housekeeping to persons with AIDS. Long-term low-cost group housing for people with AIDS is also available.

Ward 86 (SFGH AIDS Oncology Clinic)

San Francisco General Hospital
995 Potrero, San Francisco, CA 94110 (415) 821-8830
An outpatient medical clinic that specializes in caring for people with AIDS. Provides screening and referral services, comprehensive medical care, coordinates psycho-social support services, and participates in AIDS-related research.

Ward 5-B SFGH

San Francisco General Hospital
1001 Potrero, San Francisco, CA 94110 (415) 821-8153
An in-patient AIDS ward providing the specialized medical and emotional care for people with AIDS.

Women's AIDS Network

c/o San Francisco AIDS Foundation
333 Valencia Street, San Francisco, CA 94103 (415) 864-4376
Acts as a clearinghouse and information network for women about AIDS, and for women working with AIDS.

Many of these groups are DEPENDENT on volunteers and contributions for continuation of services. You or your group could volunteer time or hold a special fundraising event. There are many ways to become involved.

How will you help? We Need You!

For further information on any of the agencies listed, contact the agency directly. For information about reprints of this piece, contact the San Francisco Community Partnership on AIDS through the San Francisco AIDS Foundation.

Mr. CHAIRMAN. I want to thank each of you for testifying. This has meant a great deal to all of us and, I think, to the country at-large.

With that, we will recess until further notice.

[Whereupon, at 12:37 p.m., the committee was adjourned.]

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